Bone Marrow Aspiration, Bone Marrow Biopsy, Bone Lesion Biopsy Bibliography

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Hematology/Oncology Bibliography

Aspiration

YEAR: 2013

Falcon-Cantrill M, Thomas P, Saldivar V, Assanasen C. Comparison of a rotary powered bone marrow aspiration and biopsy device to the traditional manual device in children. Pediatr Blood Cancer 2013;60(S2);S8. Doi:10.1002/pbc.24509 113

This abstract presented at the 2013 American Society of Pediatric Hematology/Oncology Annual meeting describes a randomized study comparing bone marrow biopsy and aspiration procedures performed using the traditional manual device and the powered OnControl device in pediatric patients. The authors concluded that OnControl biopsies were obtained safely, in less time, and in good quality compared to those obtained using traditional manual devices and that the benefits may lead to reductions in anesthesia time and overall cost. This study was sponsored by Vidacare Corporation.

Kerimaa P, Marttila A, Hyvonen P. MRI-guide biopsy and fine needle aspiration biopsy (FNAB) in the diagnosis of musculoskeletal lesions. European Journal of Radiology 2013. http://dx.doi.org/10.1016/j.ejrad.2013.09.005 120

This retrospective study evaluated the diagnostic value of MRI guided percutaneous musculoskeletal biopsy and the value of fine needle aspiration biopsy when combined with histologic biopsy in 172 procedures. The authors concluded that MRI guidance produced greater diagnostic accuracy than trepine biopsy and fine needle aspiration biopsy when each are used alone.

Symington K, Martinez F, Philbeck T. Pathology examination of 64 consecutive specimens obtained using a powered biopsy device at a community based hospital. Poster presented at World Conference on Interventional Oncology 2013. http://www.wcio2013.org 115

This abstract presented at the 2013 World Conference on Interventional Oncology describes a retrospective review of 64 patients who underwent biopsy procedures performed using the OnControl system by one interventional radiology group. The authors concluded that the device was especially useful for hard bones and difficult to reach lesions, resulted in shorter procedure times with less physician effort, and that use of the device resulted in larger/higher quality specimens, a broader spectrum of potential users, and reduced radiation exposure to patients and clinicians. This study was sponsored by Vidacare Corporation.

YEAR: 2011

Higgins, R, Brenner A, Lampkin HT. Characterization of bone marrow core biopsy artifact due to aspiration: implications for technique and specimen quality. Arch Pathol Lab Med 2011;135:1179-80 85

This pre-clinical study sought to characterize aspiration artifact in the bone marrow to determine the distance from the aspirate site at which artifact would not be observed. Bone marrow aspiration of 3ml, 4ml, and 10ml were performed in the iliac crest with biopsy specimens collected in 0.5 cm intervals from the aspiration site. The iliac crest surrounding the 10 ml aspiration site was excised for evaluation. Results showed that none of the collected specimens demonstrated aspiration artifact. When evaluating the excised bone, it was noted that the artifact symmetrically affected an area of 0.4 cm wide and 1.6 cm deep; a calculated 0.2ml defect. This study was sponsored by Vidacare Corporation.

YEAR: 2010

Musolino A, Guazzi A, Nizzoli R, Panebianco M, Mancini C, Ardizzoni A. Accuracy and relative value of bone marrow aspiration in the detection of lymphoid infiltration in non-Hodgkin lymphoma. Tumori 2010;96:24-7. 52

This article evaluates the correlation between bone marrow aspirate and biopsy results in 51 patients with NHL that received both procedures simultaneously. They found that the agreement level was 80% for this patient population, with discrepancies in 20% of cases evaluated.

Swords A, Anguita J, Higgins RA et al. A new rotary powered device for bone marrow aspiration and biopsy yields superior specimens with less pain: results of a randomized clinical study. Blood 2010;116(21):650-1 3

This abstract describes a 50-patient study that compared the powered device to the traditional manual technique by relatively assessing pain scores, procedure times, biopsy capture rates, quality of material retrieved, safety and operator satisfaction. Results suggest that the use of a powered bone marrow biopsy device significantly reduces needle insertion pain. Moreover, the superior size and overall quality of core specimens retrieved by the powered device provides more material for pathologic evaluation, thereby increasing diagnostic yield and reducing the need for repeat procedures. This study was sponsored by Vidacare Corporation.

YEAR: 2008

Goldberg C, Sacher R, Vergidis D. Bone marrow aspiration and biopsy. Emedicine.medscape.com. http://emedicine.medscape.com/article/207578-print. Updated April 7, 2008 82

This article provides a detailed overview of bone marrow aspiration and biopsy from initial patient visit through processing and reporting.

YEAR: 2005

Graf BL, Korte W, Schmid L, Schmid U, Cogliatti SB. Impact of aspirate smears and trephine biopsies in routine bone marrow diagnostics: a comparative study of 141 cases. Swiss Med Wkly 2005;135:151-9. 56

Compares the diagnostic impact of bone marrow cytology in combination with flow cytometry analysis of aspirate smears and bone marrow histology together with immunohistochemical examination of trephine biopsies. Diagnoses between aspirate and biopsy were concordant in 80.5% cases.

YEAR: 2002

Nanda A, Basu S, Marwaha N. Bone marrow trephine biopsy as an adjunct to bone marrow aspiration. J Assoc Physicians India 2002;50:893-5 91

The objective of this study was to evaluate the efficacy of bone marrow aspiration as compared to bone marrow biopsy for the purpose of disease diagnosis. Of 420 consecutive cases, aspiration alone was sufficient in making a diagnosis in 372 (88.6%). In the remaining cases bilateral biopsy was required to reach a diagnosis.

Hematology/Oncology Bibliography

Aspiration

YEAR: 2001

Bain BJ. Bone marrow aspiration. J Clin Pathol 2001;54(9):657-63 74

This article provides a general overview of bone marrow aspiration including, indications and areas of controversy, site and technique, processing, and reporting.

YEAR: 1997

Barekman CL, Fair KP, Cotelingam JD. Comparative utility of diagnostic bone-marrow components: a 10 year study. Am J Hematol 1997;56:37-41 32

This article describes a 10 year study of 4,902 patients receiving bone marrow procedures to assess the value of specific components. Investigators concluded that bilateral aspirates with biopsies are needed for diagnosis in staging for neoplasms, and that a unilateral aspirate with biopsy is sufficient to assess patients with cytopenia and leukemia.

YEAR: 1992

Winfield DA, Polacarz, SV. Bone marrow histology 3: Value of bone marrow core biopsy in acute leukemia, myelodysplastic syndromes, and chronic myeloid leukemia. Journal of Clinical Pathology 1992;45:855-9 42

This article examines the role bone marrow aspirate and core biopsy play in diagnosis and regular monitoring of acute myeloblastic leukemia (AML), megakaryoblastic leukaemia and acute myelofibrosis, acute lymphoblastic leukemia (ALL), myelodysplastic syndromes (MDS), and chronic myeloid leukemia (CML). The authors conclude that a core biopsy specimen complements the peripheral blood and marrow aspirate findings in providing additional information for the diagnosis and assessment of prognosis.

YEAR: 1989

Pileri S, Poggi S, Baglioni P, Montanari M, Sabattini E, Galieni P, et al. Histology and immunohistology of bone marrow biopsy in multiple myeloma. Eur J Haematol Suppl 1989;51:52-9 53

Fixed biopsy samples from 125 multiple myeloma patients were reviewed according to morphological and immunohistological criteria. Comparison of the findings of biopsies and aspirates, the aspirate sample lead to an underestimation of the tumor burden in 30% of cases.

Abstract

YEAR: 1988

Islam A, Henderson ES. Value of long-core biopsy in the detection of discrete bone marrow lesions. Histopathology 1988;12:641-8 34

This article describes a study involving 256 bone marrow biopsy procedures, in which biopsy specimens were compared with peripheral blood smears and bone marrow aspirates. Researchers concluded that when blood and aspirate samples fail to indicate the diagnosis, a long-core biopsy may provide positive results.

YEAR: 1976

Garrett TJ, Gee TS, Lieberman PH, McKenzie S, Clarkson BD. The role of bone marrow aspiration and biopsy in detecting marrow involvement by nonhematologic malignancies. Cancer 1976;38(6):2401-3 51

This abstract describes the review of records at memorial Sloan-Kettering Cancer Center evaluating biopsy and aspirate testing. Supports both aspiration and biopsy are indicated for full evaluation of bone marrow in cancer patients.

Abstract

YEAR: 1974

Bearden JD, Ratkin GA, Coltman CA. Comparison of the diagnostic value of bone marrow biopsy and bone marrow aspiration in neoplastic disease. J Clin Pathol 1974;27:738-40 59

Evaluation of 205 simultaneously collected bone marrow biopsy and aspirate specimens from patients with lymphoma, leukemia, and a variety of solid tumors. Specimens were evaluated for adequacy, number of positive biopsies, and disparity between biopsy and aspirate.

Hematology/Oncology Bibliography

Bone Biopsy

YEAR: 2008

Hernandez JD, Wesseling K, Pereira R, Gales B, Harrison R, Salusky IB.Technical approach to iliac crest biopsy.Clin J Am Soc Nephrol 2008;3:S164-9. doi:10.2215/CJN.00460107 121

This article provides a general overview of the process of iliac crest bone biopsy including the indications, preparation, instrumentation, and potential complications, with a focus on use of the procedure for diagnosis and treatment of renal osteodystrophy.

YEAR: 2014

Symington K, Martinez F, Miller LJ, Philbeck T.Battery-powered bone biopsy system with coaxial needles: first series report.JVIR 2014;25(3s):S174-5 123

This abstract describes use of the powered OnControl Bone Access System with coaxial needles to perform 12 consecutive biopsy procedures of lytic and sclerotic bone lesions. A pathologist was present to provide assessment of the initial specimens and all were of adequate volume/cellularity. One complication of asymptomatic pneumothorax was reported; a precautionary chest tube was placed. The authors concluded the powered biopsy system/co-axial needle set reliably yields multiple large biopsy specimens of adequate cellularity.

YEAR: 2014

Symington K, Martinez F, Miller LJ, Philbeck T.Examination of 64 consecutive specimens obtained using a powered biopsy device.JVIR 2014;25(3s):S196 124

This abstract describes the initial experience of one radiology group's use of the powered OnControl system to perform biopsy of focal bone lesions and bone marrow aspiration/biopsy. The authors concluded that the powered system results in higher quality specimens, easier and faster performance of biopsy, a broader spectrum of potential users, and reduced radiation exposure to patients and operators, turning previously inaccessible focal lesions into potential biopsy targets.

YEAR: 2013

Symington K, Martinez F, Philbeck T.Pathology examination of 64 consecutive specimens obtained using a powered biopsy device at a community based hospital.Poster presented at World Conference on Interventional Oncology 2013. http://www.wcio2013.org 115

This abstract presented at the 2013 World Conference on Interventional Oncology describes a retrospective review of 64 patients who underwent biopsy procedures performed using the OnControl system by one interventional radiology group. The authors concluded that the device was especially useful for hard bones and difficult to reach lesions, resulted in shorter procedure times with less physician effort, and that use of the device resulted in larger/higher quality specimens, a broader spectrum of potential users, and reduced radiation exposure to patients and clinicians. This study was sponsored by Vidacare Corporation.

Hematology/Oncology Bibliography

Bone Marrow Biopsy and Aspirate

YEAR: 2014

Konda B, Pathak S, Edwin I, et al.Safe and successful bone marrow biopsy: an anatomical and CT-based cadaver study.American Journal of Hematology 2014;89(10):943-6. doi:10.1002/ajh.23790 125

This article describes a cadaver study comparing the perpendicular and lateral approaches for performing bone marrow biopsy procedures in the posterior iliac crest to determine if one approach is preferred. The cadavers were placed in the left and right lateral decubitus position for the procedures; the manual Jamshidi and powered needles were used. The needle pathways for each approach were evaluated under CT and the bone was dissected to evaluate structural damage. The authors found that continued advancement of the needle with the perpendicular approach was associated with an increased likelihood of injury to nearby arteries and nerves, and the sacroiliac joint with inadvertent penetration of the inner cortex. The lateral approach was found to be significantly less likely to result in neuro-vascular damage or trauma to the sacroiliac joint. The authors also note that the lateral approach yields significantly longer specimens though the data collected is limited and not specified in the article.

YEAR: 2009

Liden Y, Landgren O, Arner S, Sjöund KF, Johansson E.Procedure-related pain among adult patients with hematologic malignancies.Acta Anaesthesiol Scand 2009;53(3):354-63. doi: 10.1111/j.1399-6576.2008.01874.x 89

Prospective study of cancer patients evaluating the characteristics and determinants of procedure-related pain, with bone marrow aspiration/biopsy (BMA) as the procedure. 70% of patients reported moderate to severe pain. Predictors of pain during BMA were identified which may help identify patients in need of complementary interventions to alleviate pain.

Sweden

YEAR: 1999

Reid MM, Roald B.Deterioration in performance in obtaining bone marrow trephine biopsy cores from children.J Clin Pathol 1999;52;851-2 122

This article describes a follow up study to a prior study conducted by the same group of investigators (Reid 1996) evaluating the adequacy of bone marrow biopsy specimens obtained from children. Specimens obtained from 25 different centers were evaluated by a central pathologist and graded for adequacy. Of 605 specimens collected from 150 children with neuroblastoma, 154 specimens (25%) were deemed inadequate. The authors concluded that local initiatives involving active and direct feedback from reporting pathologists should be employed to influence operators.

UK

YEAR: 2014

Symington K, Martinez F, Miller LJ, Philbeck T.Examination of 64 consecutive specimens obtained using a powered biopsy device.JVIR 2014;25(3s):S196 124

This abstract describes the initial experience of one radiology group's use of the powered OnControl system to perform biopsy of focal bone lesions and bone marrow aspiration/biopsy. The authors concluded that the powered system results in higher quality specimens, easier and faster performance of biopsy, a broader spectrum of potential users, and reduced radiation exposure to patients and operators, turning previously inaccessible focal lesions into potential biopsy targets.

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YEAR: 2013

Voigt J, Mosier M.A powered bone marrow biopsy system versus manual methods: a systematic review and meta-analysis of randomised trials.J Clin Pathol 2013;doi:10.1136/jclinpath-2013-201605 112

Literature review and meta-analysis to determine if the OnControl powered biopsy retrieval system provides for significantly different/improved outcomes for patient pain and sample size. PubMed and Cochrane search done for randomized controlled trials that compared the OC method with manual methods was completed. Authors concluded this analysis demonstrates the OC powered system results in less patient pain and a greater amount of biopsy sample capture with similar adverse events. It also demonstrates the OC system is easy to use.

Hematology/Oncology Bibliography

Case Study

YEAR: 2014

Symington K, Martinez F, Miller LJ, Philbeck T. Battery-powered bone biopsy system with coaxial needles: first series report. JVIR 2014;25(3s):S174-5 123

This abstract describes use of the powered OnControl Bone Access System with coaxial needles to perform 12 consecutive biopsy procedures of lytic and sclerotic bone lesions. A pathologist was present to provide assessment of the initial specimens and all were of adequate volume/cellularity. One complication of asymptomatic pneumothorax was reported; a precautionary chest tube was placed. The authors concluded the powered biopsy system/co-axial needle set reliably yields multiple large biopsy specimens of adequate cellularity.

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YEAR: 2012

Falcon MG, Assanasen C, Thomas P, Saldivar V. Comparison of a rotary powered bone marrow aspiration and biopsy device to the traditional manual device in adolescent. Blood 2012;120:Abstract 4718 106

A case study of bilateral bone marrow aspiration and biopsy procedures performed on a 17-year-old female with relapsed alveolar rhabdomyosarcoma. The patient's bone marrow procedures were performed using the powered OnControl Bone Marrow Biopsy System and the manual Jamshidi needle. Results found the OnControl was superior to the manual device in terms of time to biopsy collection, time to aspirate collection, and operator satisfaction. There was no difference between the devices for number of attempts and post-procedural pain score. The manual procedure yielded a biopsy sample that was longer (9mm vs 14 mm), wider (1.5 mm vs 2mm), and of a higher quality rating (1 vs 2) than the OnControl procedure . This study was sponsored by Vidacare Corporation.

YEAR: 2007

Chamisa I. Fatal vascular retroperitoneal injury following bone marrow biopsy. SAMJ 2007;97(4):246 10

This article describes a case study in which a patient died as a result of abdominal compartment syndrome, secondary to extravasation following a bone marrow biopsy procedure.

Von Gunten CF, Soskins M. Bone marrow biopsy symptom control and palliative care consultation. J Pain Symptom Manage 2007;33(3):236-7.doi:10.1016/j.jpainsymman.2006.11.003 102

This letter to the editor describes one hospital's evaluation of patient discomfort associated with bone marrow procedures and makes a case for use of palliative care consultations in this patient population.

YEAR: 2006

Lowenthal RM, Taylor BV, Jones R, Beasley A. Severe persistent sciatic pain and weakness due to a gluteal artery pseudoaneurysm as a complication of bone marrow biopsy. Journal of Clinical Neuroscience 2006;13:384-5 14

Case study is presented describing a case of severe and debilitating sciatic nerve palsy secondary to gluteal artery pseudoaneurysm following a bone marrow biopsy procedure.

YEAR: 2005

Önal IK, Sümer H, Tufan A, Shorbagi A. Bone marrow embolism after bone marrow aspiration and biopsy. American Journal of Hematology 2005;78:158-65 20

Letter to the editor described a case of bone marrow embolism following bone marrow procedures.

YEAR: 2004

Arellano-Rodrigo E, Real MI, Muntañola A et al. Successful treatment by selective arterial embolization of severe retroperitoneal hemorrhage secondary to bone marrow biopsy in post-polycythemic myelofibrosis. Ann Hematol 2004;83:67-70 22

This case study describes endovascular approach in providing fast and minimally invasive treatment of retroperitoneal hemorrhage following bone marrow biopsy.

Hematology/Oncology Bibliography

Case Study

Farrow A, Morrison R, Pickersgill T, et al. Transient femoral neuropathy after harvest of bone from the iliac crest. British Journal of Oral and Maxillofacial Surgery 2004;42:572-4 21

This is a report of a case in which a 31-year-old woman had bone harvested from the left anterior iliac crest, and sustained a subsequent temporary femoral mononeuropathy. She later recovered completely.

Marti J, Anton E, Valenti C. Complications of bone marrow biopsy. British Journal of Haematology 2004;124:557 24

This is a letter to editor which reviews typical complications associated with bone marrow procedures and presented the case of a fatality associated with a sternal bone marrow procedure.

YEAR: 2003

Salem P, Wolverson MK, Reimers HJ, Kudva GC. Complications of bone marrow biopsy. British Journal of Haematology 2003;121:821 27

The author of this letter to editor presented two cases of hemorrhaging associated with bone marrow procedures.

YEAR: 1989

Morra E, Lazzarino M, Castello A, DInverardi D, Coci A, Pagnucco G. Bone marrow and blood involvement by non-Hodgkin's lymphoma: A study of clinicopathologic correlations and prognostic significance in relationship to the working formulation. Eur J Haematol 1989;42:445-53 67

The objective of this study was to determine the clinicopathologic correlations and impact on survival of bone marrow and peripheral blood involvement in a series of 172 cases of NHL. Results showed that the overall incidence of blood involvement by lymphoma was 28.5%; blood involvement correlated with splenomegaly, bulky disease, advance clinical stage, and extent of bone marrow infiltration.

YEAR: 1985

Ginaldi S, Williams CD. Seeding of malignant lymphoma along the tract after bone marrow biopsy. South Med J 1985;78(8):1007-8 81

In this case report, a 74 year-old man received a bone marrow biopsy for evaluation of non-Hodgkin's lymphoma. Within approximately 1 year of the bone marrow biopsy the patient was found to have developed a 6 cm tumor at the original biopsy site as a result of suspected seeding along the needle tract.

Hematology/Oncology Bibliography

Clinical, Observational and Other Studies

YEAR: 2014

Konda B, Pathak S, Edwin I, et al. Safe and successful bone marrow biopsy: an anatomical and CT-based cadaver study. American Journal of Hematology 2014;89(10):943-6. doi:10.1002/ajh.23790 125

This article describes a cadaver study comparing the perpendicular and lateral approaches for performing bone marrow biopsy procedures in the posterior iliac crest to determine if one approach is preferred. The cadavers were placed in the left and right lateral decubitus position for the procedures; the manual Jamshidi and powered needles were used. The needle pathways for each approach were evaluated under CT and the bone was dissected to evaluate structural damage. The authors found that continued advancement of the needle with the perpendicular approach was associated with an increased likelihood of injury to nearby arteries and nerves, and the sacroiliac joint with inadvertent penetration of the inner cortex. The lateral approach was found to be significantly less likely to result in neuro-vascular damage or trauma to the sacroiliac joint. The authors also note that the lateral approach yields significantly longer specimens though the data collected is limited and not specified in the article.

YEAR: 2013

Bucher CM, Lehmann T, Tichelli A, et al. Comparison of a powered bone marrow biopsy device with a manual system: results of a prospective randomised controlled trial. J Clin Pathol 2013;66:24-8. doi:10.1136/jclinpath-2012-201167 111

A prospective, randomized study conducted in Switzerland comparing the manual biopsy device to the powered OnControl device when used for bone marrow biopsy. Fifty patients were enrolled; results showed no statistical difference between the two groups for median procedure time (Manual= 180 sec; Powered=150 sec), diagnostic quality of specimen, patient reported pain (for sedated patients), patient overall satisfaction, and operator satisfaction. Subset analysis of 15 patients without sedation found statistically lower median pain scores with powered system over manual (Manual=6.3; Powered=2.9; scale 0-10, p=0.015). Authors concluded that the powered system has limited advantages over the manual system; and patients who do not wish to be sedated may be considered for use of the device.

Falcon-Cantrill M, Thomas P, Saldivar V, Assanasen C. Comparison of a rotary powered bone marrow aspiration and biopsy device to the traditional manual device in children. Pediatr Blood Cancer 2013;60(S2);S8. Doi:10.1002/pbc.24509 113

This abstract presented at the 2013 American Society of Pediatric Hematology/Oncology Annual meeting describes a randomized study comparing bone marrow biopsy and aspiration procedures performed using the traditional manual device and the powered OnControl device in pediatric patients. The authors concluded that OnControl biopsies were obtained safely, in less time, and in good quality compared to those obtained using traditional manual devices and that the benefits may lead to reductions in anesthesia time and overall cost. This study was sponsored by Vidacare Corporation.

Kerimaa P, Marttila A, Hyvonen P. MRI-guide biopsy and fine needle aspiration biopsy (FNAB) in the diagnosis of musculoskeletal lesions. European Journal of Radiology 2013. http://dx.doi.org/10.1016/j.ejrad.2013.09.005 120

This retrospective study evaluated the diagnostic value of MRI guided percutaneous musculoskeletal biopsy and the value of fine needle aspiration biopsy when combined with histologic biopsy in 172 procedures. The authors concluded that MRI guidance produced greater diagnostic accuracy than trepine biopsy and fine needle aspiration biopsy when each are used alone.

Lai K-L, Chen H-H, Wen M-C, Chen Y-M, Lan J-L, Chen D-Y. Minimally invasive ultrasound-guided synovial biopsy using core biopsy instrument. Journal of Medical Ultrasound 2013; http://dx.doi.org/10.1016/j.jmu.2013.07.004 117

A prospective study that evaluated use of the SuperCore Biopsy Instrument to perform minimally invasive ultrasound-guided synovial biopsy procedures in 22 adult patients.

Lee RK, Ng AW, Griffith JF. CT-guided bone biopsy with a battery-powered drill system: preliminary results. AJR Am J Roentgenol 2013;201(5):1093-5. doi:10.2214/AJR.12.10521 116

This prospective study evaluated use of the OnControl Coaxial Biopsy System to perform 25 CT-guided percutaneous bone biopsy procedures. Results were compared to historical manual biopsy procedure data. Data points included specimen adequacy, procedure time, number of procedural CT examinations, radiation dose, and complications. All specimens were obtained on first attempt and deemed adequate for histological diagnosis. The mean specimen length was 2.68 ± 0.68 cm; mean procedure time was 10.5 ± 3.5 minutes which is significantly less than the mean time for manual procedures of 19.4 ± 7.5 minutes. There were no complications. The authors concluded that use of the OnControl system provided a safe, quick and effective means of sampling bone lesions with minimal patient pain.

Li Y, Du Y, Luo TY, et al. Factors influencing diagnostic yield of CT-guided percutaneous core needle biopsy for bone lesions. Clinical Radiology 2013;http://dx.doi.org/10.1016/j.crad.2013.09.003 118

This study is a retrospective evaluation of 162 CT-guided bone lesion core needle biopsy procedures performed by two musculoskeletal radiologists using a standard coaxial technique. The objective of this study was to determine if factors could be identified that influence the diagnostic yield of these procedures. The authors concluded that diagnostic yield correlated with lesion type and size; and that lytic lesions and larger lesions produced higher diagnostic yield than sclerotic lesions and lesions < 3cm.

Voigt J, Mosier M. A powered bone marrow biopsy system versus manual methods: a systematic review and meta-analysis of randomised trials. J Clin Pathol 2013;doi:10.1136/jclinpath-2013-201605 112

Literature review and meta-analysis to determine if the OnControl powered biopsy retrieval system provides for significantly different/improved outcomes for patient pain and sample size. PubMed and Cochrane search done for randomized controlled trials that compared the OC method with manual methods was completed. Authors concluded this analysis demonstrates the OC powered system results in less patient pain and a greater amount of biopsy sample capture with similar adverse events. It also demonstrates the OC system is easy to use.

YEAR: 2012

Han R. "Power driver" OnControl bone biopsy device, initial experience and comparison with manual biopsy devices. Skeletal Radiology 2012;41(6):739. DOI:10.1007/s00256-012-1403-8 71

This abstract describes a retrospective analysis of one institution's initial experience with the OnControl system when used for musculoskeletal bone tumors. CT guided biopsies were performed and compared between the OnControl system, Avamax bone biopsy needle, AprioMed BoneOpty bone biopsy needle, and the Kyphon Kyphx Express bone biopsy device. Thirty-five procedures were performed using OnControl. Results showed CT guided bone biopsies performed with OnControl resulted in significantly less time to complete the procedure compared to manual bone drill devices, without a decrease in quality. No significant difference was reported between devices in radiation dose during CT guided procedure, administered anesthetic medication, or procedure related complications. The author concludes that use of the OnControl system led to improved patient care, and cost effectiveness, resulting in significant reduction in procedure time while maintaining similar safety and diagnostic quality of the specimens.

Kuivalainen AM, Pitkaniemi J, Widenisu T, Elonen E, Rosenberg P. Anxiety and pain during bone marrow aspiration and biopsy. Scandinavian Journal of Pain 2012;3:92-6. doi:10.1016/j.sjpain.2012.02.004 109

An observational study evaluating patient state of anxiety prior to a bone marrow sampling procedure and evaluating if anxiety affects the patient reported procedural pain. Results showed that pre-procedural anxiety had a major impact on pain rating; first-timers and repeat biopsy patients had similar degree of pre-procedural anxiety, as well as intensity of procedural pain; infiltration of local anesthetic was less painful with the first timers.

Liden Y, Olofsson N, Landgren O, Johansson E. Pain and anxiety during bone marrow aspiration/biopsy: comparison of ratings among patients versus health-care professionals. European Journal of Oncology Nursing 2012;16:323-9. doi:10.1016/j.ejon.2011.07.009 107

A clinical study evaluating the differences in the perception of pain and anxiety during bone marrow aspiration and biopsy procedures between the health-care professionals and the patients. Results indicated that both RNs and physicians underestimated the severe pain and anxiety for needle insertion reported by patients. Procedures were performed using the standard manual device.

YEAR: 2011

Beall DP. Powered bone access system facilitates faster vertebroplasty procedures. Skeletal Radiology 2011;40:514-5 55

This abstract describes a clinical evaluation of the Vidacare Bone Access System, used to access the vertebral body for delivery of bone cement during vertebroplasty procedures. Clinicians used the device to perform 43 vertebroplasty procedures on 40 patients. All procedures were successful and there were no complications. Conduct of this trial was sponsored by Vidacare Corporation.

Abstract

Berenson JR, Yellin O, Blumenstein B, Bojanower D, Croopnick J, Aboulafia D, et al. Using a powered bone marrow biopsy system results in shorter procedures, causes less residual pain to adult patients, and yields larger specimens. Diagnostic Pathology 2011;6:23 45

This article outlines the 102 patient, multi-center, randomized, controlled trial comparing the powered OnControl system to the standard manual technique in community-based cancer clinics. Thirteen device operators from 10 sites participated. Procedure time was significantly less for the powered device (102.1 ± 86.4 seconds) compared to the manual device (203.1 ± 149.5 seconds; p<0.001). One day following the procedure more patients were pain-free from the powered group (67%) than the manual group (33%); sample volume was larger for the powered group (36.8 mm3 ± 21.2) than the manual group (20.4 mm3 ± 9.0; p=0.039). Conduct of this trial was sponsored by Vidacare Corporation.

Berenson JR, Yellin O, Blumenstein B, Philbeck T. Rotary-powered bone marrow access results in shorter procedure time, larger core specimens and less residual pain for patients. J Vasc and Interv Radiol 2011;22(3):S15 64

This abstract describes the 102 patient, multi-center, trial comparing the powered OnControl system to the standard manual technique. Results showed procedure time was significantly less, more patients were pain free one day following the procedure, and sample volume was larger for the powered group. This trial was sponsored by Vidacare Corporation.

Abstract (Oral Presentation at 2011 SIR)

Cherington C, Robetorye R, Anderson EM et al. High quality bone marrow core biopsy and aspiration (BMBX) procedures can be performed by a nurse led team using the OnControl battery powered bone marrow biopsy system. Blood (ASH Annual Meeting Abstracts)2011;118: Abstract 4743 78

In this clinical study, a nurse-led bone marrow biopsy team evaluated the OnControl system for patient care and safety, team satisfaction and specimen quality. Ninety-four (94) bone marrow biopsy procedures were performed and specimen quality was compared to 25 manual specimens obtained by the same team. Results showed the majority of nurses felt in control of depth, were satisfied with ease of aspirate collection, felt improved ergonomics, and preferred OnControl over the manual if given a choice. All but 2 samples collected with OnControl were adequate for evaluation. The authors concluded that in the hands of experienced individuals, OnControl can consistently yield high-quality bone marrow biopsy specimens.

Miller LJ, Philbeck TE, Montez DF et al. Powered bone marrow biopsy procedures produce larger core specimens, with less pain, in less time than with standard manual devices. Hematology Reports 2011;3:e8:22-5. doi:10.4081/hr.2011.e8 90

In this study healthy volunteers were used to comparatively evaluate the powered OnControl system and the standard manual biopsy device. Each subject had a procedures performed with both devices, the order performed was randomized. Results showed samples were obtained in 66.7% of manual procedures and 100% of powered procedures (only single attempts were permitted). Mean time to sample was 86 seconds for the manual group and 47 seconds for the powered; mean second look pain score using 100mm VAS (where higher number indicate greater pain) was 33.3 for the manual and 20.9 for the powered. Pathology evaluation showed a mean sample volume of 11.0 ± 10.8mm^3;for the manual and 49.1 ± 21.5 mm^3 for the powered. This study was sponsored by Vidacare Corporation.

Reed LJ, Raghupathy R, Strakhan M et al. The OnControl bone marrow biopsy technique is superior to the standard manual technique for hematologists-in-training: a prospective, randomized comparison. Hematology Reports 2011;3(e21). doi:10.4081/hr.2011.e21 96

This article describes a 54 patient randomized controlled trial conducted at 2 academic centers comparing the OnControl powered bone marrow system and the standard manual device in a teaching hospital employing hematologists-in-training. The primary endpoint of the study, the mean length of the marrow biopsy specimens, a surrogate for marrow quality, was determined by a pathologist in a blinded manner. It was concluded that bone marrow procedures performed by hematologists-in-training were significantly faster and superior in quality when performed with the powered device compared to manual devices. These data suggest that the powered device may be considered a new standard of care for adult hematology patients. The powered device also appears to be a superior method for training hematology fellows. This study was sponsored by Vidacare Corporation.

Reed, LJ, Raghupathy R, Strakhan, M et al. The powered bone marrow biopsy technique is superior to the standard manual technique for hematologists-in-training: a prospective, randomized comparison. American Society of Hematology (ASH) December 2011; abstract 3133 95

This abstract describes a 54 patient randomized controlled trial conducted at 2 academic centers comparing the OnControl powered bone marrow system and the standard manual device in a teaching hospital employing hematologists-in-training. The primary endpoint of the study, the mean length of the marrow biopsy specimens, a surrogate for marrow quality, was determined by a pathologist in a blinded manner. It was concluded that bone marrow procedures performed by hematologists-in-training were significantly faster and superior in quality when performed with the powered device compared to manual devices. These data suggest that the powered device may be considered a new standard of care for adult hematology patients. The powered device also appears to be a superior method for training hematology fellows. This study was sponsored by Vidacare Corporation.

Swords RT, Anguita J, Higgins RA et al. A prospective randomized study of a rotary powered device (OnControl) for bone marrow aspiration and biopsy. Journal of Clinical Pathology 2011. Doi:10.1136/jclinpath-2011-200047 100

Two large academic centers participated in this prospective randomized study comparing use of the manual bone marrow biopsy device to the powered OnControl bone marrow biopsy system for collection of bone marrow biopsy specimens in adult patients. Fifty patients were enrolled into this study, 25 were assigned to the manual group and 25 were assigned to the powered group. The powered system was superior to the manual device with respect to patient perceived pain from needle insertion and procedural time. Blinded pathological evaluation indicated that specimens collected with the powered system were longer and wider than those collected with the manual device. Authors concluded that the superior size and overall quality of the specimens retrieved using the powered system provide more material for pathologic evaluation, thereby increasing diagnostic yield and reducing the need for repeat procedures.

Tanasale B, Kits J, Kluin PM, Trip A, Kluin-Nelemans HC. Pain and anxiety during bone marrow biopsy. Pain Management Nursing 2011;doi:10.1016/j.pmn.2011.06.007 110

A prospective study of 202 patients undergoing bone marrow biopsy and aspiration evaluating anxiety and pain to determine if there are factors that can predict pain score. Procedures were performed using the T-Lok bone marrow biopsy needle. The median pain score was 1.9, on a 0 to 10 scale with 21% of patients experiencing no pain at all; anxiety scored 1.8 and correlated positively with pain. The following similarities were identified among patients who reported higher pain scores: young patient age, poor performance score, prolonged procedures, and patients who were informed about the procedure by the physician. Authors concluded that bone marrow biopsies performed in an optimal setting by experienced hematologists cause only mild pain.

YEAR: 2010

Aribas BK, Dingil G, Dogan K, Sahin G, Pak I, Ardic F. Factors in sample volume and quality of CT-guided vertebral biopsy: Location and needle trajectory. Turkish Neurosurgery 2010;20(1):21-6 72

This article sought to assess sample volume and quality in CT-guided vertebral biopsy as it relates to lesion location and needle trajectory. Vertebral biopsy was performed on 48 patients requiring biopsy of various vertebral bodies. The median sample length was 10 mm; the mean sample width was 2 mm. The authors conclude that a transpedicular trajectory for biopsy had advantages over the posterolateral method as it provided longer samples.

Berenson J, Yellin O, Bojanower D et al. A multicenter randomized clinical trial comparing a powered bone marrow biopsy system and manual bone marrow biopsy procedures. Blood 2010;116(21):1571 4

This abstract describes a 102-patient multicenter randomized clinical trial that was designed to determine if a new powered bone marrow sampling device has advantages over traditional manually-inserted needles in terms of decreased pain, decreased procedure time, higher biopsy core capture rate, ease of use, improved sample yield, and higher operator satisfaction scores. Results suggest use of the powered bone marrow biopsy device markedly shortens the procedure time and reduces intermediate-term pain—important considerations for the quality of life for patients undergoing this procedure.

Abstract

Danhauer SC, Vishnevsky T, Campbell CR, et al. Music for patients with hematological malignancies undergoing bone marrow biopsy: a randomized controlled study of anxiety, perceived pain, and patient satisfaction. Journal of the Society for Integrative Oncology 2010;8(4):140-7 105

A randomized, controlled study conducted at Wake Forest University Comprehensive Cancer Center, evaluating the effect of music played during the bone marrow biopsy procedure on the patient pain and anxiety. Sixty-three (63) subjects were enrolled; Jamshidi was used to perform aspiration and biopsy; there was no significant difference between the music group and the group without music in terms of anxiety or pain. Subjects did however indicate that they highly liked the music and would prefer it on future procedures.

Degen C, Christen S, Rovo A, Gratwohl. Bone marrow examination: a prospective survey on factors associated with pain. Ann Hematol 2010;89(6):619-24 79

A single center, prospective survey of physicians performing and patients receiving bone marrow examination found pain to be the only procedure related complication. Results suggest that when patients had inadequate information about their procedure, they trended towards an association with unbearable pain.

Miller L, Philbeck T, Montez D et al. Comparing powered bone marrow biopsy procedures to manual bone marrow biopsy procedures using healthy volunteers. Blood 2010;116(21):648 2

This abstract describes a 24-subject/48-biopsy specimen study designed to determine if the powered bone-marrow biopsy device has advantages over traditional manual devices in terms of decreased pain, insertion time, and improved sample yield. Results suggest the superior size and overall quality of core specimens delivered by the powered device may provide more material for pathological evaluation of hematopoietic and oncological disorders. The powered device was significantly faster in obtaining a biopsy than the manual device and its capture rate in obtaining a satisfactory sample was much higher. Use of the powered device significantly decreases overall procedure pain.

Swords A, Anguita J, Higgins RA et al. A new rotary powered device for bone marrow aspiration and biopsy yields superior specimens with less pain: results of a randomized clinical study. Blood 2010;116(21):650-1 3

This abstract describes a 50-patient study that compared the powered device to the traditional manual technique by relatively assessing pain scores, procedure times, biopsy capture rates, quality of material retrieved, safety and operator satisfaction. Results suggest that the use of a powered bone marrow biopsy device significantly reduces needle insertion pain. Moreover, the superior size and overall quality of core specimens retrieved by the powered device provides more material for pathologic evaluation, thereby increasing diagnostic yield and reducing the need for repeat procedures. This study was sponsored by Vidacare Corporation.

Swords RT, Kelly KR, Cohen SC et al. Rotary powered device for bone marrow aspiration and biopsy yields excellent specimens quickly and efficiently. J Clin Pathol 2010;63:562-5 6

This article summarizes a preclinical study designed to determine cellular artifact or thermal damage resulting from powered bone marrow sampling and a clinical evaluation of the powered bone marrow sampling device. No cellular artifact or thermal damage was found and the device was found to be safe and easy to use, with significantly shorter procedure time than when using a manual technique.

YEAR: 2009

Liden Y, Landgren O, Arner S, Sjöund KF, Johansson E. Procedure-related pain among adult patients with hematologic malignancies. Acta Anaesthesiol Scand 2009;53(3):354-63. doi: 10.1111/j.1399-6576.2008.01874.x 89

Prospective study of cancer patients evaluating the characteristics and determinants of procedure-related pain, with bone marrow aspiration/biopsy (BMA) as the procedure. 70% of patients reported moderate to severe pain. Predictors of pain during BMA were identified which may help identify patients in need of complementary interventions to alleviate pain.

Sweden

Ruegg TA, Curran CR, Lamb T. Use of buffered lidocaine in bone marrow biopsies: A RCT: Theoretical framework. Oncology Nurse Forum 2009;36(1):52-60 62

A double-blind, randomized crossover study in which 48 patients received bilateral bone marrow biopsy procedures, one side with buffered lidocaine and one side with unbuffered lidocaine. Results showed that using 100 mm VAS (visual analog scale) pain scale, patients reported significantly lower pain scores on the buffered lidocaine side than the unbuffered lidocaine side.

Swords RT, Kelly KR, Mahalingam D, Cohen SC, Miller LJ, Philbeck TE, PhD, Hacker SO, Spadaccini CJ, Brenner A, Giles FL. Use of a new rotary powered device for bone marrow aspiration and biopsy yields excellent specimens quickly and efficiently. Blood (ASH Annual Meeting) 2009;114(22):Abstract 4544 7

This abstract summarizes a preclinical study designed to determine cellular artifact or thermal damage resulting from powered bone marrow sampling and a clinical evaluation of the powered bone marrow sampling device. No cellular artifact or thermal damage was found and the device was found to be safe and easy to use, with significantly shorter procedure time than when using a manual technique.

YEAR: 2008

Cohen SC, Gore JM. Evaluation of a powered intraosseous device for bone marrow sampling. Anticancer Research 2008;28:3843-6 104

This article discusses use of the OnControl Aspiration system in 55 patients. Successful aspirate collected in 54 of 55 patients; mean insertion time was 4.9 seconds; mean insertion pain score was 2.5. This study was sponsored by Vidacare Corporation.

Cohen SC, Soroka JM. Evaluation of a powered intraosseous device for bone marrow sampling. Biology of Blood and Marrow Transplantation 2008;14(2) s2:61. Abstract 162 8

This abstract describes an observational study designed to evaluate the ability of a new powered bone marrow aspiration device to obtain bone marrow samples. Mean needle insertion time was significantly lower than previously reported. Findings suggested the device is safe and effective.

Park SH, Bang SM, Nam E, Cho EK, Shin DB, Lee JH, et al. A randomized double-blind placebo controlled study of low-dose intravenous lorazepam to reduce procedural pain during bone marrow aspiration and biopsy. Pain Medicine 2008;9(2):249-52 47

This study evaluated the efficacy of IV lorazepam, 1mg, as premedication for bone marrow aspiration and biopsy procedures. 138 patients were enrolled, all received local 1% lidocaine and either lorazepam or placebo just before the procedure. Outcome measures included a questionnaire to determine patient perception of the procedure and pain assessments at baseline, just following the procedure, and the next day using a 10cm VAS. Results: IV lorazepam, 1mg, provides no reduction in pain associated with bone marrow aspiration biopsy procedures; more patients receiving the lorazepam reported they were more likely to agree to a second bone marrow procedure.

Welker JA, Henshaw RM, Jelinke J, Shmookler BM, Malawer MM. The percutaneous needle biopsy Is safe and recommended in the diagnosis of musculoskeletal masses. Outcomes analysis of 155 patients at a sarcoma referral center. Cancer 2000;89(12):2677-86 103

The objective of this study was to evaluate percutaneous core needle biopsy in the diagnosis of musculoskeletal sarcomas. One hundred seventy-three biopsy procedures were performed; in 88.2% of cases, a single percutaneous biopsy was adequate. Additionally, patients undergoing percutaneous biopsy rather than open biopsy had lower rates of major diagnostic errors and complications. The authors concluded that percutaneous needle biopsy was found to be extremely effective and safe for the diagnosis of musculoskeletal masses.

YEAR: 2007

Buckley O, Benfayed W, Geoghegan T, et al. CT-guided bone biopsy: Initial experience with a commercially available hand held Black and Decker™ drill. European Journal of Radiology 2007;61:176-80 9

This article describes a 68 patient study in which patients underwent bone biopsy using a Black and Decker drill to access the iliac crest. Investigators successfully obtained diagnostic material in 80% of the cases with no major complications.

Cohen SC, Soroka JM. Evaluation of a powered intraosseous device for bone marrow sampling. Blood 2007;110. Abstract 5150 11

This abstract describes an observational study designed to evaluate the ability of a new powered bone marrow aspiration device to obtain bone marrow samples. Mean needle insertion time was significantly lower than previously reported. Findings suggested the device is safe and effective.

Islam A. Bone marrow aspiration before bone marrow core biopsy using the same bone marrow biopsy needle: a good or bad practice?. J Clin Pathol 2007;60:212-5 12

This article describes a clinical study of bone marrow aspiration and core biopsy procedures in which single-needle/single-site technique was compared to a double-needle technique. Investigators found the double-needle technique to be superior.

YEAR: 2005

Naznin M, Wahab AJ, Kalavathy R. A review of bone marrow examinations in Tengku Ampuan Afzan hospital (HTAA), Kuantan. The International Medical Journal 2005;4(1). http://www.eimjm.com/vol4-No1.html 92

This retrospective study evaluated the adequacy of bone marrow aspirate and biopsy samples collected over the course of one year. Of 69 aspirations and 61 biopsies, 42% of aspirations and 32% of biopsies were found to be inadequate. The authors conclude that aspirate and biopsy samples are complementary and give a higher diagnostic yield when both are available for a patient.

YEAR: 2004

Burkle CM, Harrison BA, Koenig LF, Decker PA, Warner DO, Gastineau DA. Morbidity and mortality of deep sedation in outpatient bone marrow biopsy. American Journal of Hematology 2004;77:250-6 23

This article describes retrospective study to establish safety of deep sedation used for adults undergoing bone marrow biopsy and aspiration. Results suggest that deep sedation for outpatient bone marrow biopsy and aspiration is as safe as using local anesthetics.

Kuball J, Schuz J, Gamm H, Weber W. Bone marrow punctures and pain. Acute Pain 2004;6:9-14 17

This article describes a 263 patient study in which patients receiving bone marrow procedures were evaluated for pain. Substantial pain was reported by 30.4% of patients, but physicians did not realize the pain was felt in more than 50% of the cases. Duration of the procedure was identified as the sole independent predictive factor for patients' pain intensity.

YEAR: 2003

Vanhelleputte P, Nils K, Delforge M, Evers G, Vanderschueren S. Pain during bone marrow aspiration: prevalence and prevention. Journal of Pain and Symptom Management 2003;26(3):860-6 28

This article describes an observational study of 132 patients undergoing bone marrow aspiration procedures. Investigators concluded that the great majority of patients experience transient pain during the procedure.

YEAR: 2002

Nanda A, Basu S, Marwaha N. Bone marrow trephine biopsy as an adjunct to bone marrow aspiration. J Assoc Physicians India 2002;50:893-5 91

The objective of this study was to evaluate the efficacy of bone marrow aspiration as compared to bone marrow biopsy for the purpose of disease diagnosis. Of 420 consecutive cases, aspiration alone was sufficient in making a diagnosis in 372 (88.6%). In the remaining cases bilateral biopsy was required to reach a diagnosis.

YEAR: 2001

Goldenberg AS, Tiesinga JJ. Clinical experience with a new specimen capturing bone marrow biopsy needle. Am J Hematol 2001;68:189-93 29

This article describes an observational study in which the SNARECOIL™ needle was used for 44 patients requiring bone marrow biopsies. Of 50 procedures, 52% of the specimens were ≥2.0cm in length.

YEAR: 1999

Reid MM, Roald B. Deterioration in performance in obtaining bone marrow trephine biopsy cores from children. J Clin Pathol 1999;52;851-2 122

This article describes a follow up study to a prior study conducted by the same group of investigators (Reid 1996) evaluating the adequacy of bone marrow biopsy specimens obtained from children. Specimens obtained from 25 different centers were evaluated by a central pathologist and graded for adequacy. Of 605 specimens collected from 150 children with neuroblastoma, 154 specimens (25%) were deemed inadequate. The authors concluded that local initiatives involving active and direct feedback from reporting pathologists should be employed to influence operators.

UK

YEAR: 1997

Barekman CL, Fair KP, Cotelingam JD. Comparative utility of diagnostic bone-marrow components: a 10 year study. Am J Hematol 1997;56:37-41 32

This article describes a 10 year study of 4,902 patients receiving bone marrow procedures to assess the value of specific components. Investigators concluded that bilateral aspirates with biopsies are needed for diagnosis in staging for neoplasms, and that a unilateral aspirate with biopsy is sufficient to assess patients with cytopenia and leukemia.

YEAR: 1993

Ahlstrom KH, Astrom KGO. CT-guided bone biopsy performed by means of a coaxial biopsy system with an eccentric drill. Radiology 1993;188:549-52 33

The authors describe a 32 patient study in which a makeshift bone biopsy system, that included a power drill, was used to obtain the bone marrow sample. Successful samples were obtained in 43% of the 37 cases.

YEAR: 1988

Islam A, Henderson ES. Value of long-core biopsy in the detection of discrete bone marrow lesions. Histopathology 1988;12:641-8 34

This article describes a study involving 256 bone marrow biopsy procedures, in which biopsy specimens were compared with peripheral blood smears and bone marrow aspirates. Researchers concluded that when blood and aspirate samples fail to indicate the diagnosis, a long-core biopsy may provide positive results.

YEAR: 1983

Faugere MC, Malluche HH. Comparison of different bone-biopsy techniques for qualitative and quantitative diagnosis of metabolic bone diseases. J Bone Joint Surg Am 1983;65:1314-8 46

This study compared bone biopsy samples taken using a 3mm diameter Jamshidi needle and 5mm diameter electric drill for qualitative and quantitative study of bone histology. Statistical evaluation of the differences and correlations between histomorphometic parameters was performed; results showed that 3mm diameter samples were sufficient for qualitative diagnosis but were not optimum for the quantitative evaluation of cellular parameters of resorption and formation.

YEAR: 1982

Birch CD, Fischer S, Zibell A, Jensen ME. Diagnostic bone-marrow studies extended routinely by iliac crest biopsy, using the method of Schaadt-Fischer. Acta Pathol Microbiol Immunol Scand 1982;90:229-34 35

This article describes a study involving 129 bone marrow biopsy procedures using Schaadt-Fischer needles and technique. Authors concluded that using the technique makes it possible to obtain adequate biopsies in 80 to 90% of all patients.

YEAR: 1964

Ellis LD, Jensen WN, Westerman MP. Needle biopsy of bone and bone marrow. An experience with 1,445 biopsies. Arch Intern Med 1964;114:213-4 40

The authors describe early study of 1,445 bone marrow biopsy procedures using a modification of the Silverman needle.

YEAR: 1959

Brody JI, Finch SC. Bone marrow needle biopsy. The American Journal of Medical Sciences 1959:140-5 41

This article describes early 100-patient study of bone marrow procedures. Procedure and technique is described in great detail. With focus on patients undergoing biopsies, investigators concluded that the method is simple, safe and convenient for patients; and that the method will replace surgical procedures for obtaining bone marrow biopsies.

Hematology/Oncology Bibliography

Complications

YEAR: 2014

Symington K, Martinez F, Miller LJ, Philbeck T. Battery-powered bone biopsy system with coaxial needles: first series report. JVIR 2014;25(3s):S174-5 123

This abstract describes use of the powered OnControl Bone Access System with coaxial needles to perform 12 consecutive biopsy procedures of lytic and sclerotic bone lesions. A pathologist was present to provide assessment of the initial specimens and all were of adequate volume/cellularity. One complication of asymptomatic pneumothorax was reported; a precautionary chest tube was placed. The authors concluded the powered biopsy system/co-axial needle set reliably yields multiple large biopsy specimens of adequate cellularity.

YEAR: 2013

Voigt J, Mosier M. A powered bone marrow biopsy system versus manual methods: a systematic review and meta-analysis of randomised trials. J Clin Pathol 2013;doi:10.1136/jclinpath-2013-201605 112

Literature review and meta-analysis to determine if the OnControl powered biopsy retrieval system provides for significantly different/improved outcomes for patient pain and sample size. PubMed and Cochrane search done for randomized controlled trials that compared the OC method with manual methods was completed. Authors concluded this analysis demonstrates the OC powered system results in less patient pain and a greater amount of biopsy sample capture with similar adverse events. It also demonstrates the OC system is easy to use.

YEAR: 2011

Berenson JR, Yellin O, Blumenstein B, Bojanower D, Croopnick J, Aboulafia D, et al. Using a powered bone marrow biopsy system results in shorter procedures, causes less residual pain to adult patients, and yields larger specimens. Diagnostic Pathology 2011;6:23 45

This article outlines the 102 patient, multi-center, randomized, controlled trial comparing the powered OnControl system to the standard manual technique in community-based cancer clinics. Thirteen device operators from 10 sites participated. Procedure time was significantly less for the powered device (102.1 ± 86.4 seconds) compared to the manual device (203.1 ± 149.5 seconds; p<0.001). One day following the procedure more patients were pain-free from the powered group (67%) than the manual group (33%); sample volume was larger for the powered group (36.8 mm3 ± 21.2) than the manual group (20.4 mm3 ± 9.0; p=0.039). Conduct of this trial was sponsored by Vidacare Corporation.

Berenson JR, Yellin O, Blumenstein B, Philbeck T. Rotary-powered bone marrow access results in shorter procedure time, larger core specimens and less residual pain for patients. J Vasc and Interv Radiol 2011;22(3):S15 64

This abstract describes the 102 patient, multi-center, trial comparing the powered OnControl system to the standard manual technique. Results showed procedure time was significantly less, more patients were pain free one day following the procedure, and sample volume was larger for the powered group. This trial was sponsored by Vidacare Corporation.

Abstract (Oral Presentation at 2011 SIR)

YEAR: 2010

Berenson J, Yellin O, Bojanower D et al. A multicenter randomized clinical trial comparing a powered bone marrow biopsy system and manual bone marrow biopsy procedures. Blood 2010;116(21):1571 4

This abstract describes a 102-patient multicenter randomized clinical trial that was designed to determine if a new powered bone marrow sampling device has advantages over traditional manually-inserted needles in terms of decreased pain, decreased procedure time, higher biopsy core capture rate, ease of use, improved sample yield, and higher operator satisfaction scores. Results suggest use of the powered bone marrow biopsy device markedly shortens the procedure time and reduces intermediate-term pain—important considerations for the quality of life for patients undergoing this procedure.

Abstract

YEAR: 2009

Swords RT, Kelly KR, Mahalingam D, Cohen SC, Miller LJ, Philbeck TE, PhD, Hacker SO, Spadaccini CJ, Brenner A, Giles FL. Use of a new rotary powered device for bone marrow aspiration and biopsy yields excellent specimens quickly and efficiently. Blood (ASH Annual Meeting) 2009;114(22):Abstract 4544 7

This abstract summarizes a preclinical study designed to determine cellular artifact or thermal damage resulting from powered bone marrow sampling and a clinical evaluation of the powered bone marrow sampling device. No cellular artifact or thermal damage was found and the device was found to be safe and easy to use, with significantly shorter procedure time than when using a manual technique.

YEAR: 2008

Hernandez JD, Wesseling K, Pereira R, Gales B, Harrison R, Salusky IB. Technical approach to iliac crest biopsy. Clin J Am Soc Nephrol 2008;3:S164-9. doi:10.2215/CJN.00460107 121

This article provides a general overview of the process of iliac crest bone biopsy including the indications, preparation, instrumentation, and potential complications, with a focus on use of the procedure for diagnosis and treatment of renal osteodystrophy.

Hematology/Oncology Bibliography

Complications

YEAR: 2007

Chamisa I. Fatal vascular retroperitoneal injury following bone marrow biopsy. SAMJ 2007;97(4):246 10

This article describes a case study in which a patient died as a result of abdominal compartment syndrome, secondary to extravasation following a bone marrow biopsy procedure.

YEAR: 2006

Lowenthal RM, Taylor BV, Jones R, Beasley A. Severe persistent sciatic pain and weakness due to a gluteal artery pseudoaneurysm as a complication of bone marrow biopsy. Journal of Clinical Neuroscience 2006;13:384-5 14

Case study is presented describing a case of severe and debilitating sciatic nerve palsy secondary to gluteal artery pseudoaneurysm following a bone marrow biopsy procedure.

YEAR: 2005

Bain BJ. Bone marrow biopsy morbidity: review of 2003. J Clin Path 2005;58(4):406-8 49

This article summarizes the occurrence of adverse events associated with diagnostic bone marrow aspirates and trephine biopsies between January 1- December 31, 2003, as reported by members of the British Society of Haematology. Of 19,259 bone marrow procedures performed as reported by 63 hospitals, 16 adverse events were reported (0.08%) with 11 of them being hemorrhage.

Önal IK, Sümer H, Tufan A, Shorbagi A. Bone marrow embolism after bone marrow aspiration and biopsy. American Journal of Hematology 2005;78:158-65 20

Letter to the editor described a case of bone marrow embolism following bone marrow procedures.

YEAR: 2004

Arellano-Rodrigo E, Real MI, Muntañola A et al. Successful treatment by selective arterial embolization of severe retroperitoneal hemorrhage secondary to bone marrow biopsy in post-polycythemic myelofibrosis. Ann Hematol 2004;83:67-70 22

This case study describes endovascular approach in providing fast and minimally invasive treatment of retroperitoneal hemorrhage following bone marrow biopsy.

Farrow A, Morrison R, Pickersgill T, et al. Transient femoral neuropathy after harvest of bone from the iliac crest. British Journal of Oral and Maxillofacial Surgery 2004;42:572-4 21

This is a report of a case in which a 31-year-old woman had bone harvested from the left anterior iliac crest, and sustained a subsequent temporary femoral mononeuropathy. She later recovered completely.

Marti J, Anton E, Valenti C. Complications of bone marrow biopsy. British Journal of Haematology 2004;124:557 24

This is a letter to editor which reviews typical complications associated with bone marrow procedures and presented the case of a fatality associated with a sternal bone marrow procedure.

Riley RS, Hogan TF, Pavot DR et al. A pathologist's perspective on bone marrow aspiration and biopsy: I. Performing a bone marrow examination. J Clin Lab Anal 2004;18(2):70-90 97

This article provides an overview of performing bone marrow aspirate and biopsy examination from indications for bone marrow examination through post procedure care, including possible complications.

YEAR: 2003

Bain BJ. Bone marrow biopsy morbidity and mortality. British Journal of Haematology 2003;121:949-51 25

The author describes a postal survey of British hematologists to determine adverse event rates during bone marrow procedures. Of nearly 55,000 procedures, only 26 adverse events were reported, including one death. The most frequent and serious adverse event was hemorrhage, reported in 14 cases.

Morley NJ, Makris M. Bone marrow biopsy related haemorrhage and low molecular weight heparin. British Journal of Haematology 2003;123:561 26

The author of this letter to the editor opined that therapy with low molecular weight heparin should be considered an absolute contraindication to bone marrow biopsy.

Salem P, Wolverson MK, Reimers HJ, Kudva GC. Complications of bone marrow biopsy. British Journal of Haematology 2003;121:821 27

The author of this letter to editor presented two cases of hemorrhaging associated with bone marrow procedures.

YEAR: 2001

van Iperen CE, Cornelissen JJ. Bone marrow aspiration, a dangerous procedure?. The Netherlands Journal of Medicine 2001;59:4-5 31

In this editorial, authors briefly review precautions that should be taken to perform safe bone marrow procedures.

YEAR: 1985

Ginaldi S, Williams CD. Seeding of malignant lymphoma along the tract after bone marrow biopsy. South Med J 1985;78(8):1007-8 81

In this case report, a 74 year-old man received a bone marrow biopsy for evaluation of non-Hodgkin's lymphoma. Within approximately 1 year of the bone marrow biopsy the patient was found to have developed a 6 cm tumor at the original biopsy site as a result of suspected seeding along the needle tract.

Hematology/Oncology Bibliography

Devices

YEAR: 2014

Konda B, Pathak S, Edwin I, et al.Safe and successful bone marrow biopsy: an anatomical and CT-based cadaver study.American Journal of Hematology 2014;89(10):943-6. doi:10.1002/ajh.23790 125

This article describes a cadaver study comparing the perpendicular and lateral approaches for performing bone marrow biopsy procedures in the posterior iliac crest to determine if one approach is preferred. The cadavers were placed in the left and right lateral decubitus position for the procedures; the manual Jamshidi and powered needles were used. The needle pathways for each approach were evaluated under CT and the bone was dissected to evaluate structural damage. The authors found that continued advancement of the needle with the perpendicular approach was associated with an increased likelihood of injury to nearby arteries and nerves, and the sacroiliac joint with inadvertent penetration of the inner cortex. The lateral approach was found to be significantly less likely to result in neuro-vascular damage or trauma to the sacroiliac joint. The authors also note that the lateral approach yields significantly longer specimens though the data collected is limited and not specified in the article.

YEAR: 2013

Bucher CM, Lehmann T, Tichelli A, et al.Comparison of a powered bone marrow biopsy device with a manual system: results of a prospective randomised controlled trial.J Clin Pathol 2013;66:24-8. doi:10.1136/jclinpath-2012-201167 111

A prospective, randomized study conducted in Switzerland comparing the manual biopsy device to the powered OnControl device when used for bone marrow biopsy. Fifty patients were enrolled; results showed no statistical difference between the two groups for median procedure time (Manual= 180 sec; Powered=150 sec), diagnostic quality of specimen, patient reported pain (for sedated patients), patient overall satisfaction, and operator satisfaction. Subset analysis of 15 patients without sedation found statistically lower median pain scores with powered system over manual (Manual=6.3; Powered=2.9; scale 0-10, p=0.015). Authors concluded that the powered system has limited advantages over the manual system; and patients who do not wish to be sedated may be considered for use of the device.

Falcon-Cantrill M, Thomas P, Saldivar V, Assanasen C.Comparison of a rotary powered bone marrow aspiration and biopsy device to the traditional manual device in children.Pediatr Blood Cancer 2013;60(S2);S8. Doi:10.1002/pbc.24509 113

This abstract presented at the 2013 American Society of Pediatric Hematology/Oncology Annual meeting describes a randomized study comparing bone marrow biopsy and aspiration procedures performed using the traditional manual device and the powered OnControl device in pediatric patients. The authors concluded that OnControl biopsies were obtained safely, in less time, and in good quality compared to those obtained using traditional manual devices and that the benefits may lead to reductions in anesthesia time and overall cost. This study was sponsored by Vidacare Corporation.

Kerimaa P, Marttila A, Hyvonen P.MRI-guide biopsy and fine needle aspiration biopsy (FNAB) in the diagnosis of musculoskeletal lesions.European Journal of Radiology 2013. http://dx.doi.org/10.1016/j.ejrad.2013.09.005 120

This retrospective study evaluated the diagnostic value of MRI guided percutaneous musculoskeletal biopsy and the value of fine needle aspiration biopsy when combined with histologic biopsy in 172 procedures. The authors concluded that MRI guidance produced greater diagnostic accuracy than trepine biopsy and fine needle aspiration biopsy when each are used alone.

Lai K-L, Chen H-H, Wen M-C, Chen Y-M, Lan J-L, Chen D-Y.Minimally invasive ultrasound-guided synovial biopsy using core biopsy instrument.Journal of Medical Ultrasound 2013; http://dx.doi.org/10.1016/j.jmu.2013.07.004 117

A prospective study that evaluated use of the SuperCore Biopsy Instrument to perform minimally invasive ultrasound-guided synovial biopsy procedures in 22 adult patients.

Li Y, Du Y, Luo TY, et al.Factors influencing diagnostic yield of CT-guided percutaneous core needle biopsy for bone lesions.Clinical Radiology 2013;http://dx.doi.org/10.1016/j.crad.2013.09.003 118

This study is a retrospective evaluation of 162 CT-guided bone lesion core needle biopsy procedures performed by two musculoskeletal radiologists using a standard coaxial technique. The objective of this study was to determine if factors could be identified that influence the diagnostic yield of these procedures. The authors concluded that diagnostic yield correlated with lesion type and size; and that lytic lesions and larger lesions produced higher diagnostic yield than sclerotic lesions and lesions < 3cm.

YEAR: 2012

Abrams-Ogg AC, Defarges A, Foster RA, Bienzle D.Comparison of canine core bone marrow biopsies from multiple sites using different techniques and needles.Vet Clin Pathol 2012;41(2):235-42. doi: 10.1111/j.1939-165X.2012.00422.x 119

A pre-clinical study that compared the EZ-IO 15 gauge 25mm needle set and the 13 gauge Jamshidi aspiration/biopsy needle when used to obtain core biopsy specimens in canines.

Falcon MG, Assanasen C, Thomas P, Saldivar V.Comparison of a rotary powered bone marrow aspiration and biopsy device to the traditional manual device in adolescent.Blood 2012;120:Abstract 4718 106

A case study of bilateral bone marrow aspiration and biopsy procedures performed on a 17-year-old female with relapsed alveolar rhabdomyosarcoma. The patient's bone marrow procedures were performed using the powered OnControl Bone Marrow Biopsy System and the manual Jamshidi needle. Results found the OnControl was superior to the manual device in terms of time to biopsy collection, time to aspirate collection, and operator satisfaction. There was no difference between the devices for number of attempts and post-procedural pain score. The manual procedure yielded a biopsy sample that was longer (9mm vs 14 mm), wider (1.5 mm vs 2mm), and of a higher quality rating (1 vs 2) than the OnControl procedure . This study was sponsored by Vidacare Corporation.

Goldstein J.American Society of Hematology annual meeting: innovative device company products seen rapidly reaching exhibit floor.Medical Device Daily. December 28, 2012:1 108

This article discusses the new medical devices, including bone marrow aspiration and biopsy capture devices, shown at the ASH 2012 meeting.

Han R."Power driver" OnControl bone biopsy device, initial experience and comparison with manual biopsy devices.Skeletal Radiology 2012;41(6):739. DOI:10.1007/s00256-012-1403-8 71

This abstract describes a retrospective analysis of one institution's initial experience with the OnControl system when used for musculoskeletal bone tumors. CT guided biopsies were performed and compared between the OnControl system, Avamax bone biopsy needle, AprioMed BoneOpty bone biopsy needle, and the Kyphon Kyphx Express bone biopsy device. Thirty-five procedures were performed using OnControl. Results showed CT guided bone biopsies performed with OnControl resulted in significantly less time to complete the procedure compared to manual bone drill devices, without a decrease in quality. No significant difference was reported between devices in radiation dose during CT guided procedure, administered anesthetic medication, or procedure related complications. The author concludes that use of the OnControl system led to improved patient care, and cost effectiveness, resulting in significant reduction in procedure time while maintaining similar safety and diagnostic quality of the specimens.

YEAR: 2011

Beall DP.Powered bone access system facilitates faster vertebroplasty procedures.Skeletal Radiology 2011;40:514-5 55

This abstract describes a clinical evaluation of the Vidacare Bone Access System, used to access the vertebral body for delivery of bone cement during vertebroplasty procedures. Clinicians used the device to perform 43 vertebroplasty procedures on 40 patients. All procedures were successful and there were no complications. Conduct of this trial was sponsored by Vidacare Corporation.

Berenson JR, Yellin O, Blumenstein B, Bojanower D, Croopnick J, Aboulafia D, et al.Using a powered bone marrow biopsy system results in shorter procedures, causes less residual pain to adult patients, and yields larger specimens.Diagnostic Pathology 2011;6:23 45

This article outlines the 102 patient, multi-center, randomized, controlled trial comparing the powered OnControl system to the standard manual technique in community-based cancer clinics. Thirteen device operators from 10 sites participated. Procedure time was significantly less for the powered device (102.1 ± 86.4 seconds) compared to the manual device (203.1 ± 149.5 seconds; p<0.001). One day following the procedure more patients were pain-free from the powered group (67%) than the manual group (33%); sample volume was larger for the powered group (36.8 mm3 ± 21.2) than the manual group (20.4 mm3 ± 9.0; p=0.039). Conduct of this trial was sponsored by Vidacare Corporation.

Berenson JR, Yellin O, Blumenstein B, Philbeck T.Rotary-powered bone marrow access results in shorter procedure time, larger core specimens and less residual pain for patients.J Vasc and Interv Radiol 2011;22(3):S15 64

This abstract describes the 102 patient, multi-center, trial comparing the powered OnControl system to the standard manual technique. Results showed procedure time was significantly less, more patients were pain free one day following the procedure, and sample volume was larger for the powered group. This trial was sponsored by Vidacare Corporation.

Garcia G, Miller LJ, Philbeck, T, Bolleter S, Montez, D.Tactile feedback allows accurate insertion of a powered bone access device for vertebroplasty and bone marrow sampling procedures.J Vasc and Interv Radiol 2011;22(3):S86 63

This study evaluated the ability of the clinician to successfully insert manual driven needles, hammer driven needles, and power driven needles into simulated bone material of varying depths, to the requested depth. Placement was confirmed by fluoroscopy. Results showed insertion success with manual was 48.5%, with hammer was 69.7% and, with powered was 91%; statistically significant (p<.05). This study was sponsored by Vidacare Corporation.

Miller LJ, Philbeck TE, Montez DF et al.Powered bone marrow biopsy procedures produce larger core specimens, with less pain, in less time than with standard manual devices.Hematology Reports 2011;3:e8:22-5. doi:10.4081/hr.2011.e8 90

In this study healthy volunteers were used to comparatively evaluate the powered OnControl system and the standard manual biopsy device. Each subject had a procedures performed with both devices, the order performed was randomized. Results showed samples were obtained in 66.7% of manual procedures and 100% of powered procedures (only single attempts were permitted). Mean time to sample was 86 seconds for the manual group and 47 seconds for the powered; mean second look pain score using 100mm VAS (where higher number indicate greater pain) was 33.3 for the manual and 20.9 for the powered. Pathology evaluation showed a mean sample volume of 11.0 ± 10.8mm^3;for the manual and 49.1 ± 21.5 mm^3 for the powered. This study was sponsored by Vidacare Corporation.

Reed LJ, Raghupathy R, Strakhan M et al.The OnControl bone marrow biopsy technique is superior to the standard manual technique for hematologists-in-training: a prospective, randomized comparison.Hematology Reports 2011;3(e21). doi:10.4081/hr.2011.e21 96

This article describes a 54 patient randomized controlled trial conducted at 2 academic centers comparing the OnControl powered bone marrow system and the standard manual device in a teaching hospital employing hematologists-in-training. The primary endpoint of the study, the mean length of the marrow biopsy specimens, a surrogate for marrow quality, was determined by a pathologist in a blinded manner. It was concluded that bone marrow procedures performed by hematologists-in-training were significantly faster and superior in quality when performed with the powered device compared to manual devices. These data suggest that the powered device may be considered a new standard of care for adult hematology patients. The powered device also appears to be a superior method for training hematology fellows. This study was sponsored by Vidacare Corporation.

Reed, LJ, Raghupathy R, Strakhan, M et al.The powered bone marrow biopsy technique is superior to the standard manual technique for hematologists-in-training: a prospective, randomized comparison.American Society of Hematology (ASH) December 2011; abstract 3133 95

This abstract describes a 54 patient randomized controlled trial conducted at 2 academic centers comparing the OnControl powered bone marrow system and the standard manual device in a teaching hospital employing hematologists-in-training. The primary endpoint of the study, the mean length of the marrow biopsy specimens, a surrogate for marrow quality, was determined by a pathologist in a blinded manner. It was concluded that bone marrow procedures performed by hematologists-in-training were significantly faster and superior in quality when performed with the powered device compared to manual devices. These data suggest that the powered device may be considered a new standard of care for adult hematology patients. The powered device also appears to be a superior method for training hematology fellows. This study was sponsored by Vidacare Corporation.

Swords RT, Anguita J, Higgins RA et al.A prospective randomized study of a rotary powered device (OnControl) for bone marrow aspiration and biopsy.Journal of Clinical Pathology 2011. Doi:10.1136/jclinpath-2011-200047 100

Two large academic centers participated in this prospective randomized study comparing use of the manual bone marrow biopsy device to the powered OnControl bone marrow biopsy system for collection of bone marrow biopsy specimens in adult patients. Fifty patients were enrolled into this study, 25 were assigned to the manual group and 25 were assigned to the powered group. The powered system was superior to the manual device with respect to patient perceived pain from needle insertion and procedural time. Blinded pathological evaluation indicated that specimens collected with the powered system were longer and wider than those collected with the manual device. Authors concluded that the superior size and overall quality of the specimens retrieved using the powered system provide more material for pathologic evaluation, thereby increasing diagnostic yield and reducing the need for repeat procedures.

Tanasale B, Kits J, Kluin PM, Trip A, Kluin-Nelemans HC.Pain and anxiety during bone marrow biopsy.Pain Management Nursing 2011;doi:10.1016/j.pmn.2011.06.007 110

A prospective study of 202 patients undergoing bone marrow biopsy and aspiration evaluating anxiety and pain to determine if there are factors that can predict pain score. Procedures were performed using the T-Lok bone marrow biopsy needle. The median pain score was 1.9, on a 0 to 10 scale with 21% of patients experiencing no pain at all; anxiety scored 1.8 and correlated positively with pain. The following similarities were identified among patients who reported higher pain scores: young patient age, poor performance score, prolonged procedures, and patients who were informed about the procedure by the physician. Authors concluded that bone marrow biopsies performed in an optimal setting by experienced hematologists cause only mild pain.

YEAR: 2010

Aribas BK, Dingil G, Dogan K, Sahin G, Pak I, Ardic F.Factors in sample volume and quality of CT-guided vertebral biopsy: Location and needle trajectory.Turkish Neurosurgery 2010;20(1):21-6 72

This article sought to assess sample volume and quality in CT-guided vertebral biopsy as it relates to lesion location and needle trajectory. Vertebral biopsy was performed on 48 patients requiring biopsy of various vertebral bodies. The median sample length was 10 mm; the mean sample width was 2 mm. The authors conclude that a transpedicular trajectory for biopsy had advantages over the posterolateral method as it provided longer samples.

Berenson J, Yellin O, Bojanower D et al.A multicenter randomized clinical trial comparing a powered bone marrow biopsy system and manual bone marrow biopsy procedures.Blood 2010;116(21):1571 4

This abstract describes a 102-patient multicenter randomized clinical trial that was designed to determine if a new powered bone marrow sampling device has advantages over traditional manually-inserted needles in terms of decreased pain, decreased procedure time, higher biopsy core capture rate, ease of use, improved sample yield, and higher operator satisfaction scores. Results suggest use of the powered bone marrow biopsy device markedly shortens the procedure time and reduces intermediate-term pain—important considerations for the quality of life for patients undergoing this procedure.

Miller L, Philbeck T, Montez D et al.Comparing powered bone marrow biopsy procedures to manual bone marrow biopsy procedures using healthy volunteers.Blood 2010;116(21):648 2

This abstract describes a 24-subject/48-biopsy specimen study designed to determine if the powered bone-marrow biopsy device has advantages over traditional manual devices in terms of decreased pain, insertion time, and improved sample yield. Results suggest the superior size and overall quality of core specimens delivered by the powered device may provide more material for pathological evaluation of hematopoietic and oncological disorders. The powered device was significantly faster in obtaining a biopsy than the manual device and its capture rate in obtaining a satisfactory sample was much higher. Use of the powered device significantly decreases overall procedure pain.

Miller L.Tactile feedback comparison of manual, hammer, and rotary powered needle insertion accuracy for bone marrow biopsy and ther procedures.52nd ASH Annual Meeting and Exposition, Orlando, FL, Orange County Convention Center, December 4-7, 2010 5

This abstract describes a study designed to determine if clinicians were able to correctly place the needle tip into a specific target area of simulated bone more often and in less time when using rotary powered intraosseous devices than when using manually inserted devices, or hammer-assisted insertion devices, when relying primarily on tactile feedback to determine correct depth of penetration. Investigators concluded that correct placement of a bone biopsy needle into a precise target area using tactile feedback only was markedly better and faster when using a rotary powered needle than when using a manually inserted or a hammer assisted device.

Swords A, Anguita J, Higgins RA et al.A new rotary powered device for bone marrow aspiration and biopsy yields superior specimens with less pain: results of a randomized clinical study.Blood 2010;116(21):650-1 3

This abstract describes a 50-patient study that compared the powered device to the traditional manual technique by relatively assessing pain scores, procedure times, biopsy capture rates, quality of material retrieved, safety and operator satisfaction. Results suggest that the use of a powered bone marrow biopsy device significantly reduces needle insertion pain. Moreover, the superior size and overall quality of core specimens retrieved by the powered device provides more material for pathologic evaluation, thereby increasing diagnostic yield and reducing the need for repeat procedures. This study was sponsored by Vidacare Corporation.

Swords RT, Kelly KR, Cohen SC et al.Rotary powered device for bone marrow aspiration and biopsy yields excellent specimens quickly and efficiently. J Clin Pathol 2010;63:562-5 6

This article summarizes a preclinical study designed to determine cellular artifact or thermal damage resulting from powered bone marrow sampling and a clinical evaluation of the powered bone marrow sampling device. No cellular artifact or thermal damage was found and the device was found to be safe and easy to use, with significantly shorter procedure time than when using a manual technique.

Symington K, Martinez Jr F.Bone marrow procedures move into the 21st century.Oncology NEWS International 2010;19(9) 54

Brief history of bone marrow procedures and how the IO approach is revolutionizing the field. Discusses use of OnControl. Conduct of this trial was sponsored by Vidacare Corporation.

YEAR: 2009

Swords RT, Kelly KR, Mahalingam D, Cohen SC, Miller LJ, Philbeck TE, PhD, Hacker SO, Spadaccini CJ, Brenner A, Giles FL.Use of a new rotary powered device for bone marrow aspiration and biopsy yields excellent specimens quickly and efficiently.Blood (ASH Annual Meeting) 2009;114(22):Abstract 4544 7

This abstract summarizes a preclinical study designed to determine cellular artifact or thermal damage resulting from powered bone marrow sampling and a clinical evaluation of the powered bone marrow sampling device. No cellular artifact or thermal damage was found and the device was found to be safe and easy to use, with significantly shorter procedure time than when using a manual technique.

YEAR: 2008

Cohen SC, Gore JM.Evaluation of a powered intraosseous device for bone marrow sampling.Anticancer Research 2008;28:3843-6 104

This article discusses use of the OnControl Aspiration system in 55 patients. Successful aspirate collected in 54 of 55 patients; mean insertion time was 4.9 seconds; mean insertion pain score was 2.5. This study was sponsored by Vidacare Corporation.

Cohen SC, Soroka JM.Evaluation of a powered intraosseous device for bone marrow sampling.Biology of Blood and Marrow Transplantation 2008;14(2) s2:61. Abstract 162 8

This abstract describes an observational study designed to evaluate the ability of a new powered bone marrow aspiration device to obtain bone marrow samples. Mean needle insertion time was significantly lower than previously reported. Findings suggested the device is safe and effective.

YEAR: 2007

Buckley O, Benfayed W, Geoghegan T, et al.CT-guided bone biopsy: Initial experience with a commercially available hand held Black and Decker™ drill.European Journal of Radiology 2007;61:176-80 9

This article describes a 68 patient study in which patients underwent bone biopsy using a Black and Decker drill to access the iliac crest. Investigators successfully obtained diagnostic material in 80% of the cases with no major complications.

Cohen SC, Soroka JM.Evaluation of a powered intraosseous device for bone marrow sampling.Blood 2007;110. Abstract 5150 11

This abstract describes an observational study designed to evaluate the ability of a new powered bone marrow aspiration device to obtain bone marrow samples. Mean needle insertion time was significantly lower than previously reported. Findings suggested the device is safe and effective.

Parapia LA.Trepanning or trephanes: a history of bone marrow biopsy.British Journal of Haematology 2007;139:14-9 13

This article provides overview of history of bone marrow biopsy procedures; includes descriptions and illustrations of antique and modern biopsy devices.

Roberts CC, Morrison WB, Deely DM, Zoga AC, Koulouris G, Winalski CS.Use of a novel percutaneous biopsy localization device: initial musculoskeletal experience.Skeletal Radiol 2007;36(1):53-7. doi: 10.1007/s00256-006-0182-5 98

This article describes the preliminary use of a CT-biopsy guidance device for use in musculoskeletal applications. The authors concluded that use of the device is potentially useful for musculoskeletal applications and that the linear metal artifact produced by the device can help the device operator plan the approach for biopsy.

YEAR: 2005

Roberts C, Morrison W, Leslie K, et al.Assessment of bone biopsy needles for sample size, specimen quality and ease of use.Skeletal Radiol 2005;34:329-35 16

This article describes study in which investigators assessed the differences in ease of use and quality of samples among several bone biopsy needles, including models by Coo Elson/Ackerman, RADI, Bard, MD Tech, Parallax, and Kendall. The investigators concluded that biopsy needles vary significantly in performance; and that detailed knowledge of the strengths and weaknesses of different needles is important to make an appropriate selection.

YEAR: 2001

Goldenberg AS, Tiesinga JJ.Clinical experience with a new specimen capturing bone marrow biopsy needle.Am J Hematol 2001;68:189-93 29

This article describes an observational study in which the SNARECOIL™ needle was used for 44 patients requiring bone marrow biopsies. Of 50 procedures, 52% of the specimens were ≥2.0cm in length.

YEAR: 2000

Saifuddin A, Mitchell R, Burnett SJD, Sandison A, Pringle JAS.Utltrasound-guided needle biopsy of primary bone tumours.J Bone Joint Surg Br 2000;82-B(1):50-4 99

This study evaluated use of ultrasound guided Trucut needle biopsy in 63 patients with suspected primary bone tumors. Results showed the diagnostic accuracy of US guided biopsy was 98.4% as compared to surgical biopsy. The authors concluded that on a selected group of patients, ultrasound is a reliable technique of guidance for percutaneous needle biopsy of bone tumors.

YEAR: 1999

Goldenberg AS, Rishton M.Bone-marrow biopsy needle incorporating a snare-coil specimen-capturing device: description and preclinical studies.Biomed Instrum Technol 1999;33(6):522-9 83

This abstract describes use a tissue biopsy needle with an internal snare-coil for capturing specimen in a resin-based foam. The author concludes that further studies in patients are required to determine the impact of the snare-coil on biopsy capture.

YEAR: 1996

Reid MM, Roald B.Adequacy of bone marrow trephine biopsy specimens in children. J Clin Pathol 1996;49:226-9 57

Evaluation of 822 biopsy specimens for adequacy, collected from children with neuroblastoma over five years, from 25 centers. Found that 17% of biopsy specimens collected were inadequate.

YEAR: 1993

Ahlstrom KH, Astrom KGO.CT-guided bone biopsy performed by means of a coaxial biopsy system with an eccentric drill.Radiology 1993;188:549-52 33

The authors describe a 32 patient study in which a makeshift bone biopsy system, that included a power drill, was used to obtain the bone marrow sample. Successful samples were obtained in 43% of the 37 cases.

YEAR: 1983

Faugere MC, Malluche HH.Comparison of different bone-biopsy techniques for qualitative and quantitative diagnosis of metabolic bone diseases.J Bone Joint Surg Am 1983;65:1314-8 46

This study compared bone biopsy samples taken using a 3mm diameter Jamshidi needle and 5mm diameter electric drill for qualitative and quantitative study of bone histology. Statistical evaluation of the differences and correlations between histomorphometic parameters was performed; results showed that 3mm diameter samples were sufficient for qualitative diagnosis but were not optimum for the quantitative evaluation of cellular parameters of resorption and formation.

YEAR: 1982

Birch CD, Fischer S, Zibell A, Jensen ME.Diagnostic bone-marrow studies extended routinely by iliac crest biopsy, using the method of Schaadt-Fischer.Acta Pathol Microbiol Immunol Scand 1982;90:229-34 35

This article describes a study involving 129 bone marrow biopsy procedures using Schaadt-Fischer needles and technique. Authors concluded that using the technique makes it possible to obtain adequate biopsies in 80 to 90% of all patients.

Islam A.A new bone marrow biopsy needle with core securing device.J Clin Pathol 1982;35:359-64 36

The author describes a bone marrow biopsy needle he designed, and the technique for using the needle.

YEAR: 1980

Knowles S, Hoffbrand AV.Bone-marrow aspiration and trephine biopsy (1).Br Med J 1980;281:204-5 37

This article (Part 1 of 2) describes bone marrow procedures in general, including techniques, preparation for slides, devices (Jamshidi-Swain), risks, and aftercare.

Knowles S, Hoffbrand AV.Bone-marrow aspiration and trephine biopsy (2).Br Med J 1980;281:280-1 38

This article (Part 2 of 2) describes bone marrow procedures in general, including techniques, preparation for slides, devices (Jamshidi-Swain), risks, and aftercare.

YEAR: 1971

Jamshidi K, Swaim WR.Bone marrow biopsy with unaltered architecture: a new biopsy device.J Lab Clin Med 1971:77;335-42 39

The authors describe their new biopsy device.

Jamshidi K, Windschitl HE, Swaim WR.A new biopsy needle for bone marrow.Scand J Haemat 1971;8:69-71 87

This article describes the first clinical use of the Jamshidi biopsy needle, newly developed at the time of this article.

YEAR: 1964

Ellis LD, Jensen WN, Westerman MP.Needle biopsy of bone and bone marrow. An experience with 1,445 biopsies.Arch Intern Med 1964;114:213-4 40

The authors describe early study of 1,445 bone marrow biopsy procedures using a modification of the Silverman needle.

Hematology/Oncology Bibliography

Harvesting

YEAR: 2006

Smiler D, Soltan M. Bone marrow aspiration: technique, grafts and reports. Implant Dentistry 2006;15(3):229-35 15

This article describes a technique for obtaining adult stem cells from bone marrow aspirate.

YEAR: 2004

Kuball J, Schuz J, Gamm H, Weber W. Bone marrow punctures and pain. Acute Pain 2004;6:9-14 17

This article describes a 263 patient study in which patients receiving bone marrow procedures were evaluated for pain. Substantial pain was reported by 30.4% of patients, but physicians did not realize the pain was felt in more than 50% of the cases. Duration of the procedure was identified as the sole independent predictive factor for patients' pain intensity.

YEAR: 1983

Faugere MC, Malluche HH. Comparison of different bone-biopsy techniques for qualitative and quantitative diagnosis of metabolic bone diseases. J Bone Joint Surg Am 1983;65:1314-8 46

This study compared bone biopsy samples taken using a 3mm diameter Jamshidi needle and 5mm diameter electric drill for qualitative and quantitative study of bone histology. Statistical evaluation of the differences and correlations between histomorphometic parameters was performed; results showed that 3mm diameter samples were sufficient for qualitative diagnosis but were not optimum for the quantitative evaluation of cellular parameters of resorption and formation.

Hematology/Oncology Bibliography

International

YEAR: 2013

Kerimaa P, Marttila A, Hyvonen P. MRI-guide biopsy and fine needle aspiration biopsy (FNAB) in the diagnosis of musculoskeletal lesions. European Journal of Radiology 2013. http://dx.doi.org/10.1016/j.ejrad.2013.09.005 120

This retrospective study evaluated the diagnostic value of MRI guided percutaneous musculoskeletal biopsy and the value of fine needle aspiration biopsy when combined with histologic biopsy in 172 procedures. The authors concluded that MRI guidance produced greater diagnostic accuracy than trepine biopsy and fine needle aspiration biopsy when each are used alone.

Li Y, Du Y, Luo TY, et al. Factors influencing diagnostic yield of CT-guided percutaneous core needle biopsy for bone lesions. Clinical Radiology 2013;http://dx.doi.org/10.1016/j.crad.2013.09.003 118

This study is a retrospective evaluation of 162 CT-guided bone lesion core needle biopsy procedures performed by two musculoskeletal radiologists using a standard coaxial technique. The objective of this study was to determine if factors could be identified that influence the diagnostic yield of these procedures. The authors concluded that diagnostic yield correlated with lesion type and size; and that lytic lesions and larger lesions produced higher diagnostic yield than sclerotic lesions and lesions < 3cm.

Lai K-L, Chen H-H, Wen M-C, Chen Y-M, Lan J-L, Chen D-Y. Minimally invasive ultrasound-guided synovial biopsy using core biopsy instrument. Journal of Medical Ultrasound 2013; http://dx.doi.org/10.1016/j.jmu.2013.07.004 117

A prospective study that evaluated use of the SuperCore Biopsy Instrument to perform minimally invasive ultrasound-guided synovial biopsy procedures in 22 adult patients.

Lee RK, Ng AW, Griffith JF. CT-guided bone biopsy with a battery-powered drill system: preliminary results. AJR Am J Roentgenol 2013;201(5):1093-5. doi:10.2214/AJR.12.10521 116

This prospective study evaluated use of the OnControl Coaxial Biopsy System to perform 25 CT-guided percutaneous bone biopsy procedures. Results were compared to historical manual biopsy procedure data. Data points included specimen adequacy, procedure time, number of procedural CT examinations, radiation dose, and complications. All specimens were obtained on first attempt and deemed adequate for histological diagnosis. The mean specimen length was 2.68 ± 0.68 cm; mean procedure time was 10.5 ± 3.5 minutes which is significantly less than the mean time for manual procedures of 19.4 ± 7.5 minutes. There were no complications. The authors concluded that use of the OnControl system provided a safe, quick and effective means of sampling bone lesions with minimal patient pain.

Bucher CM, Lehmann T, Tichelli A, et al. Comparison of a powered bone marrow biopsy device with a manual system: results of a prospective randomised controlled trial. J Clin Pathol 2013;66:24-8. doi:10.1136/jclinpath-2012-201167 111

A prospective, randomized study conducted in Switzerland comparing the manual biopsy device to the powered OnControl device when used for bone marrow biopsy. Fifty patients were enrolled; results showed no statistical difference between the two groups for median procedure time (Manual= 180 sec; Powered=150 sec), diagnostic quality of specimen, patient reported pain (for sedated patients), patient overall satisfaction, and operator satisfaction. Subset analysis of 15 patients without sedation found statistically lower median pain scores with powered system over manual (Manual=6.3; Powered=2.9; scale 0-10, p=0.015). Authors concluded that the powered system has limited advantages over the manual system; and patients who do not wish to be sedated may be considered for use of the device.

YEAR: 2012

Abrams-Ogg AC, Defarges A, Foster RA, Bienzle D. Comparison of canine core bone marrow biopsies from multiple sites using different techniques and needles. Vet Clin Pathol 2012;41(2):235-42. doi: 10.1111/j.1939-165X.2012.00422.x 119

A pre-clinical study that compared the EZ-IO 15 gauge 25mm needle set and the 13 gauge Jamshidi aspiration/biopsy needle when used to obtain core biopsy specimens in canines.

Kuivalainen AM, Pitkaniemi J, Widenisu T, Elonen E, Rosenberg P. Anxiety and pain during bone marrow aspiration and biopsy. Scandinavian Journal of Pain 2012;3:92-6. doi:10.1016/j.sjpain.2012.02.004 109

An observational study evaluating patient state of anxiety prior to a bone marrow sampling procedure and evaluating if anxiety affects the patient reported procedural pain. Results showed that pre-procedural anxiety had a major impact on pain rating; first-timers and repeat biopsy patients had similar degree of pre-procedural anxiety, as well as intensity of procedural pain; infiltration of local anesthetic was less painful with the first timers.

Liden Y, Olofsson N, Landgren O, Johansson E. Pain and anxiety during bone marrow aspiration/biopsy: comparison of ratings among patients versus health-care professionals. European Journal of Oncology Nursing 2012;16:323-9. doi:10.1016/j.ejon.2011.07.009 107

A clinical study evaluating the differences in the perception of pain and anxiety during bone marrow aspiration and biopsy procedures between the health-care professionals and the patients. Results indicated that both RNs and physicians underestimated the severe pain and anxiety for needle insertion reported by patients. Procedures were performed using the standard manual device.

Hematology/Oncology Bibliography

International

YEAR: 2011

Tanasale B, Kits J, Kluin PM, Trip A, Kluin-Nelemans HC. Pain and anxiety during bone marrow biopsy. Pain Management Nursing 2011;doi:10.1016/j.pmn.2011.06.007 110

A prospective study of 202 patients undergoing bone marrow biopsy and aspiration evaluating anxiety and pain to determine if there are factors that can predict pain score. Procedures were performed using the T-Lok bone marrow biopsy needle. The median pain score was 1.9, on a 0 to 10 scale with 21% of patients experiencing no pain at all; anxiety scored 1.8 and correlated positively with pain. The following similarities were identified among patients who reported higher pain scores: young patient age, poor performance score, prolonged procedures, and patients who were informed about the procedure by the physician. Authors concluded that bone marrow biopsies performed in an optimal setting by experienced hematologists cause only mild pain.

YEAR: 2009

Liden Y, Landgren O, Arner S, Sjöund KF, Johansson E. Procedure-related pain among adult patients with hematologic malignancies. Acta Anaesthesiol Scand 2009;53(3):354-63. doi: 10.1111/j.1399-6576.2008.01874.x 89

Prospective study of cancer patients evaluating the characteristics and determinants of procedure-related pain, with bone marrow aspiration/biopsy (BMA) as the procedure. 70% of patients reported moderate to severe pain. Predictors of pain during BMA were identified which may help identify patients in need of complementary interventions to alleviate pain.

Sweden

YEAR: 1999

Reid MM, Roald B. Deterioration in performance in obtaining bone marrow trephine biopsy cores from children. J Clin Pathol 1999;52;851-2 122

This article describes a follow up study to a prior study conducted by the same group of investigators (Reid 1996) evaluating the adequacy of bone marrow biopsy specimens obtained from children. Specimens obtained from 25 different centers were evaluated by a central pathologist and graded for adequacy. Of 605 specimens collected from 150 children with neuroblastoma, 154 specimens (25%) were deemed inadequate. The authors concluded that local initiatives involving active and direct feedback from reporting pathologists should be employed to influence operators.

UK

Hematology/Oncology Bibliography

OnControl Biopsy Aspirate and Bone Marrow

YEAR: 2014

Konda B, Pathak S, Edwin I, et al.Safe and successful bone marrow biopsy: an anatomical and CT-based cadaver study.American Journal of Hematology 2014;89(10):943-6. doi:10.1002/ajh.23790 125

This article describes a cadaver study comparing the perpendicular and lateral approaches for performing bone marrow biopsy procedures in the posterior iliac crest to determine if one approach is preferred. The cadavers were placed in the left and right lateral decubitus position for the procedures; the manual Jamshidi and powered needles were used. The needle pathways for each approach were evaluated under CT and the bone was dissected to evaluate structural damage. The authors found that continued advancement of the needle with the perpendicular approach was associated with an increased likelihood of injury to nearby arteries and nerves, and the sacroiliac joint with inadvertent penetration of the inner cortex. The lateral approach was found to be significantly less likely to result in neuro-vascular damage or trauma to the sacroiliac joint. The authors also note that the lateral approach yields significantly longer specimens though the data collected is limited and not specified in the article.

Symington K, Martinez F, Miller LJ, Philbeck T.Examination of 64 consecutive specimens obtained using a powered biopsy device.JVIR 2014;25(3s):S196 124

This abstract describes the initial experience of one radiology group's use of the powered OnControl system to perform biopsy of focal bone lesions and bone marrow aspiration/biopsy. The authors concluded that the powered system results in higher quality specimens, easier and faster performance of biopsy, a broader spectrum of potential users, and reduced radiation exposure to patients and operators, turning previously inaccessible focal lesions into potential biopsy targets.

YEAR: 2013

Falcon-Cantrill M, Thomas P, Saldivar V, Assanasen C.Comparison of a rotary powered bone marrow aspiration and biopsy device to the traditional manual device in children.Pediatr Blood Cancer 2013;60(S2);S8. Doi:10.1002/pbc.24509 113

This abstract presented at the 2013 American Society of Pediatric Hematology/Oncology Annual meeting describes a randomized study comparing bone marrow biopsy and aspiration procedures performed using the traditional manual device and the powered OnControl device in pediatric patients. The authors concluded that OnControl biopsies were obtained safely, in less time, and in good quality compared to those obtained using traditional manual devices and that the benefits may lead to reductions in anesthesia time and overall cost. This study was sponsored by Vidacare Corporation.

Symington K, Martinez F, Philbeck T.Pathology examination of 64 consecutive specimens obtained using a powered biopsy device at a community based hospital.Poster presented at World Conference on Interventional Oncology 2013. http://www.wcio2013.org 115

This abstract presented at the 2013 World Conference on Interventional Oncology describes a retrospective review of 64 patients who underwent biopsy procedures performed using the OnControl system by one interventional radiology group. The authors concluded that the device was especially useful for hard bones and difficult to reach lesions, resulted in shorter procedure times with less physician effort, and that use of the device resulted in larger/higher quality specimens, a broader spectrum of potential users, and reduced radiation exposure to patients and clinicians. This study was sponsored by Vidacare Corporation.

Voigt J, Mosier M.A powered bone marrow biopsy system versus manual methods: a systematic review and meta-analysis of randomised trials.J Clin Pathol 2013;doi:10.1136/jclinpath-2013-201605 112

Literature review and meta-analysis to determine if the OnControl powered biopsy retrieval system provides for significantly different/improved outcomes for patient pain and sample size. PubMed and Cochrane search done for randomized controlled trials that compared the OC method with manual methods was completed. Authors concluded this analysis demonstrates the OC powered system results in less patient pain and a greater amount of biopsy sample capture with similar adverse events. It also demonstrates the OC system is easy to use.

Hematology/Oncology Bibliography

OnControl Biopsy Aspirate and Bone Marrow

YEAR: 2012

Han R."Power driver" OnControl bone biopsy device, initial experience and comparison with manual biopsy devices.Skeletal Radiology 2012;41(6):739. DOI:10.1007/s00256-012-1403-8 71

This abstract describes a retrospective analysis of one institution's initial experience with the OnControl system when used for musculoskeletal bone tumors. CT guided biopsies were performed and compared between the OnControl system, Avamax bone biopsy needle, AprioMed BoneOpty bone biopsy needle, and the Kyphon Kyphx Express bone biopsy device. Thirty-five procedures were performed using OnControl. Results showed CT guided bone biopsies performed with OnControl resulted in significantly less time to complete the procedure compared to manual bone drill devices, without a decrease in quality. No significant difference was reported between devices in radiation dose during CT guided procedure, administered anesthetic medication, or procedure related complications. The author concludes that use of the OnControl system led to improved patient care, and cost effectiveness, resulting in significant reduction in procedure time while maintaining similar safety and diagnostic quality of the specimens.

YEAR: 2011

Berenson JR, Yellin O, Blumenstein B, Bojanower D, Croopnick J, Aboulafia D, et al.Using a powered bone marrow biopsy system results in shorter procedures, causes less residual pain to adult patients, and yields larger specimens.Diagnostic Pathology 2011;6:23 45

This article outlines the 102 patient, multi-center, randomized, controlled trial comparing the powered OnControl system to the standard manual technique in community-based cancer clinics. Thirteen device operators from 10 sites participated. Procedure time was significantly less for the powered device (102.1 ± 86.4 seconds) compared to the manual device (203.1 ± 149.5 seconds; p<0.001). One day following the procedure more patients were pain-free from the powered group (67%) than the manual group (33%); sample volume was larger for the powered group (36.8 mm3 ± 21.2) than the manual group (20.4 mm3 ± 9.0; p=0.039). Conduct of this trial was sponsored by Vidacare Corporation.

Berenson JR, Yellin O, Blumenstein B, Philbeck T.Rotary-powered bone marrow access results in shorter procedure time, larger core specimens and less residual pain for patients.J Vasc and Interv Radiol 2011;22(3):S15 64

This abstract describes the 102 patient, multi-center, trial comparing the powered OnControl system to the standard manual technique. Results showed procedure time was significantly less, more patients were pain free one day following the procedure, and sample volume was larger for the powered group. This trial was sponsored by Vidacare Corporation.

Cherington C, Robetorye R, Anderson EM et al.High quality bone marrow core biopsy and aspiration (BMBX) procedures can be performed by a nurse led team using the OnControl battery powered bone marrow biopsy system.Blood (ASH Annual Meeting Abstracts)2011;118: Abstract 4743 78

In this clinical study, a nurse-led bone marrow biopsy team evaluated the OnControl system for patient care and safety, team satisfaction and specimen quality. Ninety-four (94) bone marrow biopsy procedures were performed and specimen quality was compared to 25 manual specimens obtained by the same team. Results showed the majority of nurses felt in control of depth, were satisfied with ease of aspirate collection, felt improved ergonomics, and preferred OnControl over the manual if given a choice. All but 2 samples collected with OnControl were adequate for evaluation. The authors concluded that in the hands of experienced individuals, OnControl can consistently yield high-quality bone marrow biopsy specimens.

Higgins, R, Brenner A, Lampkin HT.Characterization of bone marrow core biopsy artifact due to aspiration: implications for technique and specimen quality.Arch Pathol Lab Med 2011;135:1179-80 85

This pre-clinical study sought to characterize aspiration artifact in the bone marrow to determine the distance from the aspirate site at which artifact would not be observed. Bone marrow aspiration of 3ml, 4ml, and 10ml were performed in the iliac crest with biopsy specimens collected in 0.5 cm intervals from the aspiration site. The iliac crest surrounding the 10 ml aspiration site was excised for evaluation. Results showed that none of the collected specimens demonstrated aspiration artifact. When evaluating the excised bone, it was noted that the artifact symmetrically affected an area of 0.4 cm wide and 1.6 cm deep; a calculated 0.2ml defect. This study was sponsored by Vidacare Corporation.

Miller LJ, Philbeck TE, Montez DF et al.Powered bone marrow biopsy procedures produce larger core specimens, with less pain, in less time than with standard manual devices.Hematology Reports 2011;3:e8:22-5. doi:10.4081/hr.2011.e8 90

In this study healthy volunteers were used to comparatively evaluate the powered OnControl system and the standard manual biopsy device. Each subject had a procedures performed with both devices, the order performed was randomized. Results showed samples were obtained in 66.7% of manual procedures and 100% of powered procedures (only single attempts were permitted). Mean time to sample was 86 seconds for the manual group and 47 seconds for the powered; mean second look pain score using 100mm VAS (where higher number indicate greater pain) was 33.3 for the manual and 20.9 for the powered. Pathology evaluation showed a mean sample volume of 11.0 ± 10.8mm³;for the manual and 49.1 ± 21.5 mm³ for the powered. This study was sponsored by Vidacare Corporation.

Reed LJ, Raghupathy R, Strakhan M et al.The OnControl bone marrow biopsy technique is superior to the standard manual technique for hematologists-in-training: a prospective, randomized comparison.Hematology Reports 2011;3(e21). doi:10.4081/hr.2011.e21 96

This article describes a 54 patient randomized controlled trial conducted at 2 academic centers comparing the OnControl powered bone marrow system and the standard manual device in a teaching hospital employing hematologists-in-training. The primary endpoint of the study, the mean length of the marrow biopsy specimens, a surrogate for marrow quality, was determined by a pathologist in a blinded manner. It was concluded that bone marrow procedures performed by hematologists-in-training were significantly faster and superior in quality when performed with the powered device compared to manual devices. These data suggest that the powered device may be considered a new standard of care for adult hematology patients. The powered device also appears to be a superior method for training hematology fellows. This study was sponsored by Vidacare Corporation.

Reed, LJ, Raghupathy R, Strakhan, M et al.The powered bone marrow biopsy technique is superior to the standard manual technique for hematologists-in-training: a prospective, randomized comparison.American Society of Hematology (ASH) December 2011; abstract 3133 95

This abstract describes a 54 patient randomized controlled trial conducted at 2 academic centers comparing the OnControl powered bone marrow system and the standard manual device in a teaching hospital employing hematologists-in-training. The primary endpoint of the study, the mean length of the marrow biopsy specimens, a surrogate for marrow quality, was determined by a pathologist in a blinded manner. It was concluded that bone marrow procedures performed by hematologists-in-training were significantly faster and superior in quality when performed with the powered device compared to manual devices. These data suggest that the powered device may be considered a new standard of care for adult hematology patients. The powered device also appears to be a superior method for training hematology fellows. This study was sponsored by Vidacare Corporation.

Swords RT, Anguita J, Higgins RA et al.A prospective randomized study of a rotary powered device (OnControl) for bone marrow aspiration and biopsy.Journal of Clinical Pathology 2011. Doi:10.1136/jclinpath-2011-200047 100

Two large academic centers participated in this prospective randomized study comparing use of the manual bone marrow biopsy device to the powered OnControl bone marrow biopsy system for collection of bone marrow biopsy specimens in adult patients. Fifty patients were enrolled into this study, 25 were assigned to the manual group and 25 were assigned to the powered group. The powered system was superior to the manual device with respect to patient perceived pain from needle insertion and procedural time. Blinded pathological evaluation indicated that specimens collected with the powered system were longer and wider than those collected with the manual device. Authors concluded that the superior size and overall quality of the specimens retrieved using the powered system provide more material for pathologic evaluation, thereby increasing diagnostic yield and reducing the need for repeat procedures.

YEAR: 2010

Berenson J, Yellin O, Bojanower D et al.A multicenter randomized clinical trial comparing a powered bone marrow biopsy system and manual bone marrow biopsy procedures.Blood 2010;116(21):1571 4

This abstract describes a 102-patient multicenter randomized clinical trial that was designed to determine if a new powered bone marrow sampling device has advantages over traditional manually-inserted needles in terms of decreased pain, decreased procedure time, higher biopsy core capture rate, ease of use, improved sample yield, and higher operator satisfaction scores. Results suggest use of the powered bone marrow biopsy device markedly shortens the procedure time and reduces intermediate-term pain—important considerations for the quality of life for patients undergoing this procedure.

Swords A, Anguita J, Higgins RA et al.A new rotary powered device for bone marrow aspiration and biopsy yields superior specimens with less pain: results of a randomized clinical study.Blood 2010;116(21):650-1 3

This abstract describes a 50-patient study that compared the powered device to the traditional manual technique by relatively assessing pain scores, procedure times, biopsy capture rates, quality of material retrieved, safety and operator satisfaction. Results suggest that the use of a powered bone marrow biopsy device significantly reduces needle insertion pain. Moreover, the superior size and overall quality of core specimens retrieved by the powered device provides more material for pathologic evaluation, thereby increasing diagnostic yield and reducing the need for repeat procedures. This study was sponsored by Vidacare Corporation.

Swords RT, Kelly KR, Cohen SC et al.Rotary powered device for bone marrow aspiration and biopsy yields excellent specimens quickly and efficiently. J Clin Pathol 2010;63:562-5 6

This article summarizes a preclinical study designed to determine cellular artifact or thermal damage resulting from powered bone marrow sampling and a clinical evaluation of the powered bone marrow sampling device. No cellular artifact or thermal damage was found and the device was found to be safe and easy to use, with significantly shorter procedure time than when using a manual technique.

Symington K, Martinez Jr F.Bone marrow procedures move into the 21st century.Oncology NEWS International 2010;19(9) 54

Brief history of bone marrow procedures and how the IO approach is revolutionizing the field. Discusses use of OnControl. Conduct of this trial was sponsored by Vidacare Corporation.

YEAR: 2009

Brenner A, Miller L, Philbeck T, Hacker S.Bone marrow sampling using a rotary powered device yields excellent biopsy specimens in an animal model.Haematologica 2009; 94(s2) 76

This pre-clinical study evaluated the quality and length of bone marrow core biopsy samples acquired using the powered OnControl device and the standard manual device. Thirty-three samples were collected. An interim pathology report of 13 samples (8 powered; 5 manual) indicated no cellular damage or other significant artifact for either device. The mean length of sample for the powered group was 22.2 ± 10.8mm; the mean length of sample for the manual group was 12.7 ± 6.8mm. This study was sponsored by Vidacare Corporation.

Swords RT, Kelly KR, Mahalingam D, Cohen SC, Miller LJ, Philbeck TE, PhD, Hacker SO, Spadaccini CJ, Brenner A, Giles FL.Use of a new rotary powered device for bone marrow aspiration and biopsy yields excellent specimens quickly and efficiently.Blood (ASH Annual Meeting) 2009;114(22):Abstract 4544 7

This abstract summarizes a preclinical study designed to determine cellular artifact or thermal damage resulting from powered bone marrow sampling and a clinical evaluation of the powered bone marrow sampling device. No cellular artifact or thermal damage was found and the device was found to be safe and easy to use, with significantly shorter procedure time than when using a manual technique.

YEAR: 2008

Cohen SC, Gore JM.Evaluation of a powered intraosseous device for bone marrow sampling.Anticancer Research 2008;28:3843-6 104

This article discusses use of the OnControl Aspiration system in 55 patients. Successful aspirate collected in 54 of 55 patients; mean insertion time was 4.9 seconds; mean insertion pain score was 2.5. This study was sponsored by Vidacare Corporation.

Cohen SC, Soroka JM.Evaluation of a powered intraosseous device for bone marrow sampling.Biology of Blood and Marrow Transplantation 2008;14(2) s2:61. Abstract 162 8

This abstract describes an observational study designed to evaluate the ability of a new powered bone marrow aspiration device to obtain bone marrow samples. Mean needle insertion time was significantly lower than previously reported. Findings suggested the device is safe and effective.

YEAR: 2007

Cohen SC, Soroka JM.Evaluation of a powered intraosseous device for bone marrow sampling.Blood 2007;110. Abstract 5150 11

This abstract describes an observational study designed to evaluate the ability of a new powered bone marrow aspiration device to obtain bone marrow samples. Mean needle insertion time was significantly lower than previously reported. Findings suggested the device is safe and effective.

Islam A.Bone marrow aspiration before bone marrow core biopsy using the same bone marrow biopsy needle: a good or bad practice?. J Clin Pathol 2007;60:212-5 12

This article describes a clinical study of bone marrow aspiration and core biopsy procedures in which single-needle/single-site technique was compared to a double-needle technique. Investigators found the double-needle technique to be superior.

Hematology/Oncology Bibliography

OnControl Bone Access

YEAR: 2014

Symington K, Martinez F, Miller LJ, Philbeck T.Battery-powered bone biopsy system with coaxial needles: first series report.JVIR 2014;25(3s):S174-5 123

This abstract describes use of the powered OnControl Bone Access System with coaxial needles to perform 12 consecutive biopsy procedures of lytic and sclerotic bone lesions. A pathologist was present to provide assessment of the initial specimens and all were of adequate volume/cellularity. One complication of asymptomatic pneumothorax was reported; a precautionary chest tube was placed. The authors concluded the powered biopsy system/co-axial needle set reliably yields multiple large biopsy specimens of adequate cellularity.

Symington K, Martinez F, Miller LJ, Philbeck T.Examination of 64 consecutive specimens obtained using a powered biopsy device.JVIR 2014;25(3s):S196 124

This abstract describes the initial experience of one radiology group's use of the powered OnControl system to perform biopsy of focal bone lesions and bone marrow aspiration/biopsy. The authors concluded that the powered system results in higher quality specimens, easier and faster performance of biopsy, a broader spectrum of potential users, and reduced radiation exposure to patients and operators, turning previously inaccessible focal lesions into potential biopsy targets.

YEAR: 2013

Lee RK, Ng AW, Griffith JF.CT-guided bone biopsy with a battery-powered drill system: preliminary results.AJR Am J Roentgenol 2013;201(5):1093-5. doi:10.2214/AJR.12.10521 116

This prospective study evaluated use of the OnControl Coaxial Biopsy System to perform 25 CT-guided percutaneous bone biopsy procedures. Results were compared to historical manual biopsy procedure data. Data points included specimen adequacy, procedure time, number of procedural CT examinations, radiation dose, and complications. All specimens were obtained on first attempt and deemed adequate for histological diagnosis. The mean specimen length was 2.68 ± 0.68 cm; mean procedure time was 10.5 ± 3.5 minutes which is significantly less than the mean time for manual procedures of 19.4 ± 7.5 minutes. There were no complications. The authors concluded that use of the OnControl system provided a safe, quick and effective means of sampling bone lesions with minimal patient pain.

YEAR: 2011

Beall DP.Powered bone access system facilitates faster vertebroplasty procedures.Skeletal Radiology 2011;40:514-5 55

This abstract describes a clinical evaluation of the Vidacare Bone Access System, used to access the vertebral body for delivery of bone cement during vertebroplasty procedures. Clinicians used the device to perform 43 vertebroplasty procedures on 40 patients. All procedures were successful and there were no complications. Conduct of this trial was sponsored by Vidacare Corporation.

Garcia G, Miller LJ, Philbeck, T, Bolleter S, Montez, D.Tactile feedback allows accurate insertion of a powered bone access device for vertebroplasty and bone marrow sampling procedures.J Vasc and Interv Radiol 2011;22(3):S86 63

This study evaluated the ability of the clinician to successfully insert manual driven needles, hammer driven needles, and power driven needles into simulated bone material of varying depths, to the requested depth. Placement was confirmed by fluoroscopy. Results showed insertion success with manual was 48.5%, with hammer was 69.7% and, with powered was 91%; statistically significant (p<.05). This study was sponsored by Vidacare Corporation.

Hematology/Oncology Bibliography

Overview

YEAR: 2013

Symington K, Martinez F, Philbeck T. Pathology examination of 64 consecutive specimens obtained using a powered biopsy device at a community based hospital. Poster presented at World Conference on Interventional Oncology 2013. http://www.wcio2013.org 115

This abstract presented at the 2013 World Conference on Interventional Oncology describes a retrospective review of 64 patients who underwent biopsy procedures performed using the OnControl system by one interventional radiology group. The authors concluded that the device was especially useful for hard bones and difficult to reach lesions, resulted in shorter procedure times with less physician effort, and that use of the device resulted in larger/higher quality specimens, a broader spectrum of potential users, and reduced radiation exposure to patients and clinicians. This study was sponsored by Vidacare Corporation.

YEAR: 2011

Beall DP. Powered bone access system facilitates faster vertebroplasty procedures. Skeletal Radiology 2011;40:514-5 55

This abstract describes a clinical evaluation of the Vidacare Bone Access System, used to access the vertebral body for delivery of bone cement during vertebroplasty procedures. Clinicians used the device to perform 43 vertebroplasty procedures on 40 patients. All procedures were successful and there were no complications. Conduct of this trial was sponsored by Vidacare Corporation.

Abstract

Wilkins BS. Pitfalls in bone marrow pathology: avoiding errors in bone marrow trephine biopsy diagnosis. J Clin Pathol 2011.doi:10.1136/jcp.2010.080838 58

Description of steps necessary and common errors to avoid for correct reporting of bone marrow trephine specimens.

YEAR: 2010

Smucker JD, Akhavan S, Furey C. Understanding bony safety zones in the posterior iliac crest; an anatomic study from the Hamann-Todd collection. Spine 2010;35(7):725-9 48

This article describes the dimensions of the posterior iliac crest region in the human pelvis through analysis of 100 male and female skeletal specimens aged 18 to 80 years. There were no statistically significant differences found between right and left ilia; overall measurements were found to be significantly smaller in women.

Symington K, Martinez Jr F. Bone marrow procedures move into the 21st century. Oncology NEWS International 2010;19(9) 54

Brief history of bone marrow procedures and how the IO approach is revolutionizing the field. Discusses use of OnControl. Conduct of this trial was sponsored by Vidacare Corporation.

YEAR: 2008

Abla O, Friedman J, Doyle J. Performing bone marrow aspiration and biopsy in children: Recommended guidelines. Paediatr Child Health 2008;13(6):499-501 44

This article provides guidelines for the performance of bone marrow aspiration and trephine biopsies in children. It is intended to be useful for both general pediatricians and pediatric hematologists and oncologists. The departmental procedure and guideline document is included in the publication.

Espinosa L, Jamadar DA, Jacobson JA et al. CT-guided biopsy of bone: a radiologist's perspective. AJR Am J Roentgenol 2008 May;190(5):W283-9.doi:10.2214/AJR.07.3138 80

This article provides an overview of approaches for bone biopsy used to minimize potential tumor seeding of surrounding structures. Methods for biopsy of various anatomical locations are included.

Goldberg C, Sacher R, Vergidis D. Bone marrow aspiration and biopsy. Emedicine.medscape.com. http://emedicine.medscape.com/article/207578-print. Updated April 7, 2008 82

This article provides a detailed overview of bone marrow aspiration and biopsy from initial patient visit through processing and reporting.

Hasserjian RP. Reactive versus neoplastic bone marrow. Arch Pathol Lab Med 2008;132:587-94 84

This article provides an overview of how excellent diagnostic samples, appropriate ancillary testing, and knowledge of clinical context provide the pathologist with ability to distinguish between common reactive and neoplastic processes that involve bone marrow.

Hernandez JD, Wesseling K, Pereira R, Gales B, Harrison R, Salusky IB. Technical approach to iliac crest biopsy. Clin J Am Soc Nephrol 2008;3:S164-9. doi:10.2215/CJN.00460107 121

This article provides a general overview of the process of iliac crest bone biopsy including the indications, preparation, instrumentation, and potential complications, with a focus on use of the procedure for diagnosis and treatment of renal osteodystrophy.

YEAR: 2007

Parapia LA. Trepanning or trephanes: a history of bone marrow biopsy. British Journal of Haematology 2007;139:14-9 13

This article provides overview of history of bone marrow biopsy procedures; includes descriptions and illustrations of antique and modern biopsy devices.

YEAR: 2006

Orazi A, O'Malley D, Arber D. Illustrated pathology of the bone marrow. Cambridge University Press 2006. http://www.cambridge.org/9780521810036 94

An overview of indications and methods for bone marrow examination.

YEAR: 2004

Riley RS, Hogan TF, Pavot DR et al. A pathologist's perspective on bone marrow aspiration and biopsy: I. Performing a bone marrow examination. J Clin Lab Anal 2004;18(2):70-90 97

This article provides an overview of performing bone marrow aspirate and biopsy examination from indications for bone marrow examination through post procedure care, including possible complications.

YEAR: 2003

National Institute for Clinical Excellence (NICE). Guidance on cancer services improving outcomes in haematological cancers. The manual. http://www.nice.org.uk. Published 2003 93

An overview of managing haematological cancers.

YEAR: 2001

Bain BJ. Bone marrow aspiration. J Clin Pathol 2001;54(9):657-63 74

This article provides a general overview of bone marrow aspiration including, indications and areas of controversy, site and technique, processing, and reporting.

Bain BJ. Bone marrow trephine biopsy. J Clin Pathol 2001;54(10):737-42 73

The author provided a general overview of bone marrow trephine biopsy that including, indications and areas of controversy, site and technique, determining adequacy, processing, and reporting.

Trewhitt KG. Bone marrow aspiration and biopsy: collection and interpretation. ONF 2001;28(9):1409-17 30

The authors described the role of oncology nurse practioners in the performance of bone marrow procedures; and discusses the indications and diagnostic value of the procedures

YEAR: 1999

Cheson BD, Horning SJ, Coiffier B, Shipp MA, Fisher RI, Connors JM, et al. Report of an international workshop to standardize response criteria for Non-Hodgkin's Lymphomas. J Clin Oncol 1999;17(4):1244-53 65

In an attempt to develop standardization among clinicians, lymphoma investigators from NCI formed cooperative groups and established a consensus on a standardized set of guidelines for response assessment in adult patients with indolent and aggressive NHL. This document was subsequently reviewed and approved by European lymphoma experts.

Hematology/Oncology Bibliography

Overview

YEAR: 1988

Hyun BH, Gulati GL, Ashton JK. Bone marrow examination: techniques and interpretation. Hematol Oncol Clin of North America 1988;2(4):513-23 86

This article provides an overview of bone marrow examination.

YEAR: 1984

Koepke JA. Examination of the bone marrow. Laboratory Hematology 1984:1023-50 101

This article provides an overview of bone marrow examination from indication through processing and final report.

YEAR: 1980

Knowles S, Hoffbrand AV. Bone-marrow aspiration and trephine biopsy (1). Br Med J 1980;281:204-5 37

This article (Part 1 of 2) describes bone marrow procedures in general, including techniques, preparation for slides, devices (Jamshidi-Swain), risks, and aftercare.

Knowles S, Hoffbrand AV. Bone-marrow aspiration and trephine biopsy (2). Br Med J 1980;281:280-1 38

This article (Part 2 of 2) describes bone marrow procedures in general, including techniques, preparation for slides, devices (Jamshidi-Swain), risks, and aftercare.

YEAR: 1959

Brody JI, Finch SC. Bone marrow needle biopsy. The American Journal of Medical Sciences 1959:140-5 41

This article describes early 100-patient study of bone marrow procedures. Procedure and technique is described in great detail. With focus on patients undergoing biopsies, investigators concluded that the method is simple, safe and convenient for patients; and that the method will replace surgical procedures for obtaining bone marrow biopsies.

Hematology/Oncology Bibliography

Pain Management

YEAR: 2013

Bucher CM, Lehmann T, Tichelli A, et al. Comparison of a powered bone marrow biopsy device with a manual system: results of a prospective randomised controlled trial. J Clin Pathol 2013;66:24-8. doi:10.1136/jclinpath-2012-201167 111

A prospective, randomized study conducted in Switzerland comparing the manual biopsy device to the powered OnControl device when used for bone marrow biopsy. Fifty patients were enrolled; results showed no statistical difference between the two groups for median procedure time (Manual= 180 sec; Powered=150 sec), diagnostic quality of specimen, patient reported pain (for sedated patients), patient overall satisfaction, and operator satisfaction. Subset analysis of 15 patients without sedation found statistically lower median pain scores with powered system over manual (Manual=6.3; Powered=2.9; scale 0-10, p=0.015). Authors concluded that the powered system has limited advantages over the manual system; and patients who do not wish to be sedated may be considered for use of the device.

Lee RK, Ng AW, Griffith JF. CT-guided bone biopsy with a battery-powered drill system: preliminary results. AJR Am J Roentgenol 2013;201(5):1093-5. doi:10.2214/AJR.12.10521 116

This prospective study evaluated use of the OnControl Coaxial Biopsy System to perform 25 CT-guided percutaneous bone biopsy procedures. Results were compared to historical manual biopsy procedure data. Data points included specimen adequacy, procedure time, number of procedural CT examinations, radiation dose, and complications. All specimens were obtained on first attempt and deemed adequate for histological diagnosis. The mean specimen length was 2.68 ± 0.68 cm; mean procedure time was 10.5 ± 3.5 minutes which is significantly less than the mean time for manual procedures of 19.4 ± 7.5 minutes. There were no complications. The authors concluded that use of the OnControl system provided a safe, quick and effective means of sampling bone lesions with minimal patient pain.

Voigt J, Mosier M. A powered bone marrow biopsy system versus manual methods: a systematic review and meta-analysis of randomised trials. J Clin Pathol 2013;doi:10.1136/jclinpath-2013-201605 112

Literature review and meta-analysis to determine if the OnControl powered biopsy retrieval system provides for significantly different/improved outcomes for patient pain and sample size. PubMed and Cochrane search done for randomized controlled trials that compared the OC method with manual methods was completed. Authors concluded this analysis demonstrates the OC powered system results in less patient pain and a greater amount of biopsy sample capture with similar adverse events. It also demonstrates the OC system is easy to use.

YEAR: 2012

Kuivalainen AM, Pitkaniemi J, Widenisu T, Elonen E, Rosenberg P. Anxiety and pain during bone marrow aspiration and biopsy. Scandinavian Journal of Pain 2012;3:92-6. doi:10.1016/j.sjpain.2012.02.004 109

An observational study evaluating patient state of anxiety prior to a bone marrow sampling procedure and evaluating if anxiety affects the patient reported procedural pain. Results showed that pre-procedural anxiety had a major impact on pain rating; first-timers and repeat biopsy patients had similar degree of pre-procedural anxiety, as well as intensity of procedural pain; infiltration of local anesthetic was less painful with the first timers.

Liden Y, Olofsson N, Landgren O, Johansson E. Pain and anxiety during bone marrow aspiration/biopsy: comparison of ratings among patients versus health-care professionals. European Journal of Oncology Nursing 2012;16:323-9. doi:10.1016/j.ejon.2011.07.009 107

A clinical study evaluating the differences in the perception of pain and anxiety during bone marrow aspiration and biopsy procedures between the health-care professionals and the patients. Results indicated that both RNs and physicians underestimated the severe pain and anxiety for needle insertion reported by patients. Procedures were performed using the standard manual device.

YEAR: 2011

Berenson JR, Yellin O, Blumenstein B, Bojanower D, Croopnick J, Aboulafia D, et al. Using a powered bone marrow biopsy system results in shorter procedures, causes less residual pain to adult patients, and yields larger specimens. Diagnostic Pathology 2011;6:23 45

This article outlines the 102 patient, multi-center, randomized, controlled trial comparing the powered OnControl system to the standard manual technique in community-based cancer clinics. Thirteen device operators from 10 sites participated. Procedure time was significantly less for the powered device (102.1 ± 86.4 seconds) compared to the manual device (203.1 ± 149.5 seconds; p<0.001). One day following the procedure more patients were pain-free from the powered group (67%) than the manual group (33%); sample volume was larger for the powered group (36.8 mm3 ± 21.2) than the manual group (20.4 mm3 ± 9.0; p=0.039). Conduct of this trial was sponsored by Vidacare Corporation.

Berenson JR, Yellin O, Blumenstein B, Philbeck T. Rotary-powered bone marrow access results in shorter procedure time, larger core specimens and less residual pain for patients. J Vasc and Interv Radiol 2011;22(3):S15 64

This abstract describes the 102 patient, multi-center, trial comparing the powered OnControl system to the standard manual technique. Results showed procedure time was significantly less, more patients were pain free one day following the procedure, and sample volume was larger for the powered group. This trial was sponsored by Vidacare Corporation.

Abstract (Oral Presentation at 2011 SIR)

Miller LJ, Philbeck TE, Montez DF et al. Powered bone marrow biopsy procedures produce larger core specimens, with less pain, in less time than with standard manual devices. Hematology Reports 2011;3:e8:22-5. doi:10.4081/hr.2011.e8 90

In this study healthy volunteers were used to comparatively evaluate the powered OnControl system and the standard manual biopsy device. Each subject had a procedures performed with both devices, the order performed was randomized. Results showed samples were obtained in 66.7% of manual procedures and 100% of powered procedures (only single attempts were permitted). Mean time to sample was 86 seconds for the manual group and 47 seconds for the powered; mean second look pain score using 100mm VAS (where higher number indicate greater pain) was 33.3 for the manual and 20.9 for the powered. Pathology evaluation showed a mean sample volume of 11.0 ± 10.8mm³;for the manual and 49.1 ± 21.5 mm³ for the powered. This study was sponsored by Vidacare Corporation.

Reed LJ, Raghupathy R, Strakhan M et al. The OnControl bone marrow biopsy technique is superior to the standard manual technique for hematologists-in-training: a prospective, randomized comparison. Hematology Reports 2011;3(e21). doi:10.4081/hr.2011.e21 96

This article describes a 54 patient randomized controlled trial conducted at 2 academic centers comparing the OnControl powered bone marrow system and the standard manual device in a teaching hospital employing hematologists-in-training. The primary endpoint of the study, the mean length of the marrow biopsy specimens, a surrogate for marrow quality, was determined by a pathologist in a blinded manner. It was concluded that bone marrow procedures performed by hematologists-in-training were significantly faster and superior in quality when performed with the powered device compared to manual devices. These data suggest that the powered device may be considered a new standard of care for adult hematology patients. The powered device also appears to be a superior method for training hematology fellows. This study was sponsored by Vidacare Corporation.

Swords RT, Anguita J, Higgins RA et al. A prospective randomized study of a rotary powered device (OnControl) for bone marrow aspiration and biopsy. Journal of Clinical Pathology 2011. Doi:10.1136/jclinpath-2011-200047 100

Two large academic centers participated in this prospective randomized study comparing use of the manual bone marrow biopsy device to the powered OnControl bone marrow biopsy system for collection of bone marrow biopsy specimens in adult patients. Fifty patients were enrolled into this study, 25 were assigned to the manual group and 25 were assigned to the powered group. The powered system was superior to the manual device with respect to patient perceived pain from needle insertion and procedural time. Blinded pathological evaluation indicated that specimens collected with the powered system were longer and wider than those collected with the manual device. Authors concluded that the superior size and overall quality of the specimens retrieved using the powered system provide more material for pathologic evaluation, thereby increasing diagnostic yield and reducing the need for repeat procedures.

Tanasale B, Kits J, Kluin PM, Trip A, Kluin-Nelemans HC. Pain and anxiety during bone marrow biopsy. Pain Management Nursing 2011;doi:10.1016/j.pmn.2011.06.007 110

A prospective study of 202 patients undergoing bone marrow biopsy and aspiration evaluating anxiety and pain to determine if there are factors that can predict pain score. Procedures were performed using the T-Lok bone marrow biopsy needle. The median pain score was 1.9, on a 0 to 10 scale with 21% of patients experiencing no pain at all; anxiety scored 1.8 and correlated positively with pain. The following similarities were identified among patients who reported higher pain scores: young patient age, poor performance score, prolonged procedures, and patients who were informed about the procedure by the physician. Authors concluded that bone marrow biopsies performed in an optimal setting by experienced hematologists cause only mild pain.

YEAR: 2010

Berenson J, Yellin O, Bojanower D et al. A multicenter randomized clinical trial comparing a powered bone marrow biopsy system and manual bone marrow biopsy procedures. Blood 2010;116(21):1571 4

This abstract describes a 102-patient multicenter randomized clinical trial that was designed to determine if a new powered bone marrow sampling device has advantages over traditional manually-inserted needles in terms of decreased pain, decreased procedure time, higher biopsy core capture rate, ease of use, improved sample yield, and higher operator satisfaction scores. Results suggest use of the powered bone marrow biopsy device markedly shortens the procedure time and reduces intermediate-term pain—important considerations for the quality of life for patients undergoing this procedure.

Abstract

Danhauer SC, Vishnevsky T, Campbell CR, et al. Music for patients with hematological malignancies undergoing bone marrow biopsy: a randomized controlled study of anxiety, perceived pain, and patient satisfaction. Journal of the Society for Integrative Oncology 2010;8(4):140-7 105

A randomized, controlled study conducted at Wake Forest University Comprehensive Cancer Center, evaluating the effect of music played during the bone marrow biopsy procedure on the patient pain and anxiety. Sixty-three (63) subjects were enrolled; Jamshidi was used to perform aspiration and biopsy; there was no significant difference between the music group and the group without music in terms of anxiety or pain. Subjects did however indicate that they highly liked the music and would prefer it on future procedures.

Degen C, Christen S, Rovo A, Gratwohl. Bone marrow examination: a prospective survey on factors associated with pain. Ann Hematol 2010;89(6):619-24 79

A single center, prospective survey of physicians performing and patients receiving bone marrow examination found pain to be the only procedure related complication. Results suggest that when patients had inadequate information about their procedure, they trended towards an association with unbearable pain.

Miller L, Philbeck T, Montez D et al. Comparing powered bone marrow biopsy procedures to manual bone marrow biopsy procedures using healthy volunteers. Blood 2010;116(21):648 2

This abstract describes a 24-subject/48-biopsy specimen study designed to determine if the powered bone-marrow biopsy device has advantages over traditional manual devices in terms of decreased pain, insertion time, and improved sample yield. Results suggest the superior size and overall quality of core specimens delivered by the powered device may provide more material for pathological evaluation of hematopoietic and oncological disorders. The powered device was significantly faster in obtaining a biopsy than the manual device and its capture rate in obtaining a satisfactory sample was much higher. Use of the powered device significantly decreases overall procedure pain.

Swords A, Anguita J, Higgins RA et al. A new rotary powered device for bone marrow aspiration and biopsy yields superior specimens with less pain: results of a randomized clinical study. Blood 2010;116(21):650-1 3

This abstract describes a 50-patient study that compared the powered device to the traditional manual technique by relatively assessing pain scores, procedure times, biopsy capture rates, quality of material retrieved, safety and operator satisfaction. Results suggest that the use of a powered bone marrow biopsy device significantly reduces needle insertion pain. Moreover, the superior size and overall quality of core specimens retrieved by the powered device provides more material for pathologic evaluation, thereby increasing diagnostic yield and reducing the need for repeat procedures. This study was sponsored by Vidacare Corporation.

YEAR: 2009

Liden Y, Landgren O, Arner S, Sjöund KF, Johansson E. Procedure-related pain among adult patients with hematologic malignancies. Acta Anaesthesiol Scand 2009;53(3):354-63. doi: 10.1111/j.1399-6576.2008.01874.x 89

Prospective study of cancer patients evaluating the characteristics and determinants of procedure-related pain, with bone marrow aspiration/biopsy (BMA) as the procedure. 70% of patients reported moderate to severe pain. Predictors of pain during BMA were identified which may help identify patients in need of complementary interventions to alleviate pain.

Sweden

Ruegg TA, Curran CR, Lamb T. Use of buffered lidocaine in bone marrow biopsies: A RCT: Theoretical framework. Oncology Nurse Forum 2009;36(1):52-60 62

A double-blind, randomized crossover study in which 48 patients received bilateral bone marrow biopsy procedures, one side with buffered lidocaine and one side with unbuffered lidocaine. Results showed that using 100 mm VAS (visual analog scale) pain scale, patients reported significantly lower pain scores on the buffered lidocaine side than the unbuffered lidocaine side.

YEAR: 2008

Cohen SC, Gore JM. Evaluation of a powered intraosseous device for bone marrow sampling. Anticancer Research 2008;28:3843-6 104

This article discusses use of the OnControl Aspiration system in 55 patients. Successful aspirate collected in 54 of 55 patients; mean insertion time was 4.9 seconds; mean insertion pain score was 2.5. This study was sponsored by Vidacare Corporation.

Cohen SC, Soroka JM. Evaluation of a powered intraosseous device for bone marrow sampling. Biology of Blood and Marrow Transplantation 2008;14(2) s2:61. Abstract 162 8

This abstract describes an observational study designed to evaluate the ability of a new powered bone marrow aspiration device to obtain bone marrow samples. Mean needle insertion time was significantly lower than previously reported. Findings suggested the device is safe and effective.

Park SH, Bang SM, Nam E, Cho EK, Shin DB, Lee JH, et al. A randomized double-blind placebo controlled study of low-dose intravenous lorazepam to reduce procedural pain during bone marrow aspiration and biopsy. Pain Medicine 2008;9(2):249-52 47

This study evaluated the efficacy of IV lorazepam, 1mg, as premedication for bone marrow aspiration and biopsy procedures. 138 patients were enrolled, all received local 1% lidocaine and either lorazepam or placebo just before the procedure. Outcome measures included a questionnaire to determine patient perception of the procedure and pain assessments at baseline, just following the procedure, and the next day using a 10cm VAS. Results: IV lorazepam, 1mg, provides no reduction in pain associated with bone marrow aspiration biopsy procedures; more patients receiving the lorazepam reported they were more likely to agree to a second bone marrow procedure.

YEAR: 2007

Cohen SC, Soroka JM. Evaluation of a powered intraosseous device for bone marrow sampling. Blood 2007;110. Abstract 5150 11

This abstract describes an observational study designed to evaluate the ability of a new powered bone marrow aspiration device to obtain bone marrow samples. Mean needle insertion time was significantly lower than previously reported. Findings suggested the device is safe and effective.

Von Gunten CF, Soskins M. Bone marrow biopsy symptom control and palliative care consultation. J Pain Symptom Manage 2007;33(3):236-7.doi:10.1016/j.jpainsymman.2006.11.003 102

This letter to the editor describes one hospital's evaluation of patient discomfort associated with bone marrow procedures and makes a case for use of palliative care consultations in this patient population.

YEAR: 2005

Iannalfi A, Bernini G, Caprilli S, Lippi A, Tucci F, Messeri A. Painful procedures in children with cancer: comparison of moderate sedation and general anesthesia for lumbar puncture and bone marrow aspiration. Pediatr Blood Cancer 2005;45:933-8 19

This article describes a study comparing moderate sedation to general anesthesia in the management of frequently performed lumbar puncture or bone marrow aspiration during cancer treatment for children. Study suggests moderate sedation compared favorably with general anesthesia.

YEAR: 2004

Kuball J, Schuz J, Gamm H, Weber W. Bone marrow punctures and pain. Acute Pain 2004;6:9-14 17

This article describes a 263 patient study in which patients receiving bone marrow procedures were evaluated for pain. Substantial pain was reported by 30.4% of patients, but physicians did not realize the pain was felt in more than 50% of the cases. Duration of the procedure was identified as the sole independent predictive factor for patients' pain intensity.

Hematology/Oncology Bibliography

Pathology

YEAR: 2014

Konda B, Pathak S, Edwin I, et al.Safe and successful bone marrow biopsy: an anatomical and CT-based cadaver study.American Journal of Hematology 2014;89(10):943-6. doi:10.1002/ajh.23790 125

This article describes a cadaver study comparing the perpendicular and lateral approaches for performing bone marrow biopsy procedures in the posterior iliac crest to determine if one approach is preferred. The cadavers were placed in the left and right lateral decubitus position for the procedures; the manual Jamshidi and powered needles were used. The needle pathways for each approach were evaluated under CT and the bone was dissected to evaluate structural damage. The authors found that continued advancement of the needle with the perpendicular approach was associated with an increased likelihood of injury to nearby arteries and nerves, and the sacroiliac joint with inadvertent penetration of the inner cortex. The lateral approach was found to be significantly less likely to result in neuro-vascular damage or trauma to the sacroiliac joint. The authors also note that the lateral approach yields significantly longer specimens though the data collected is limited and not specified in the article.

Symington K, Martinez F, Miller LJ, Philbeck T.Battery-powered bone biopsy system with coaxial needles: first series report.JVIR 2014;25(3s):S174-5 123

This abstract describes use of the powered OnControl Bone Access System with coaxial needles to perform 12 consecutive biopsy procedures of lytic and sclerotic bone lesions. A pathologist was present to provide assessment of the initial specimens and all were of adequate volume/cellularity. One complication of asymptomatic pneumothorax was reported; a precautionary chest tube was placed. The authors concluded the powered biopsy system/co-axial needle set reliably yields multiple large biopsy specimens of adequate cellularity.

Symington K, Martinez F, Miller LJ, Philbeck T.Examination of 64 consecutive specimens obtained using a powered biopsy device.JVIR 2014;25(3s):S196 124

This abstract describes the initial experience of one radiology group's use of the powered OnControl system to perform biopsy of focal bone lesions and bone marrow aspiration/biopsy. The authors concluded that the powered system results in higher quality specimens, easier and faster performance of biopsy, a broader spectrum of potential users, and reduced radiation exposure to patients and operators, turning previously inaccessible focal lesions into potential biopsy targets.

YEAR: 2013

Kerimaa P, Marttila A, Hyvonen P.MRI-guide biopsy and fine needle aspiration biopsy (FNAB) in the diagnosis of musculoskeletal lesions.European Journal of Radiology 2013. http://dx.doi.org/10.1016/j.ejrad.2013.09.005 120

This retrospective study evaluated the diagnostic value of MRI guided percutaneous musculoskeletal biopsy and the value of fine needle aspiration biopsy when combined with histologic biopsy in 172 procedures. The authors concluded that MRI guidance produced greater diagnostic accuracy than trepine biopsy and fine needle aspiration biopsy when each are used alone.

Lee RK, Ng AW, Griffith JF.CT-guided bone biopsy with a battery-powered drill system: preliminary results.AJR Am J Roentgenol 2013;201(5):1093-5. doi:10.2214/AJR.12.10521 116

This prospective study evaluated use of the OnControl Coaxial Biopsy System to perform 25 CT-guided percutaneous bone biopsy procedures. Results were compared to historical manual biopsy procedure data. Data points included specimen adequacy, procedure time, number of procedural CT examinations, radiation dose, and complications. All specimens were obtained on first attempt and deemed adequate for histological diagnosis. The mean specimen length was 2.68 ± 0.68 cm; mean procedure time was 10.5 ± 3.5 minutes which is significantly less than the mean time for manual procedures of 19.4 ± 7.5 minutes. There were no complications. The authors concluded that use of the OnControl system provided a safe, quick and effective means of sampling bone lesions with minimal patient pain.

Li Y, Du Y, Luo TY, et al.Factors influencing diagnostic yield of CT-guided percutaneous core needle biopsy for bone lesions.Clinical Radiology 2013;http://dx.doi.org/10.1016/j.crad.2013.09.003 118

This study is a retrospective evaluation of 162 CT-guided bone lesion core needle biopsy procedures performed by two musculoskeletal radiologists using a standard coaxial technique. The objective of this study was to determine if factors could be identified that influence the diagnostic yield of these procedures. The authors concluded that diagnostic yield correlated with lesion type and size; and that lytic lesions and larger lesions produced higher diagnostic yield than sclerotic lesions and lesions < 3cm.

Symington K, Martinez F, Philbeck T.Pathology examination of 64 consecutive specimens obtained using a powered biopsy device at a community based hospital.Poster presented at World Conference on Interventional Oncology 2013. http://www.wcio2013.org 115

This abstract presented at the 2013 World Conference on Interventional Oncology describes a retrospective review of 64 patients who underwent biopsy procedures performed using the OnControl system by one interventional radiology group. The authors concluded that the device was especially useful for hard bones and difficult to reach lesions, resulted in shorter procedure times with less physician effort, and that use of the device resulted in larger/higher quality specimens, a broader spectrum of potential users, and reduced radiation exposure to patients and clinicians. This study was sponsored by Vidacare Corporation.

Voigt J, Mosier M.A powered bone marrow biopsy system versus manual methods: a systematic review and meta-analysis of randomised trials.J Clin Pathol 2013;doi:10.1136/jclinpath-2013-201605 112

Literature review and meta-analysis to determine if the OnControl powered biopsy retrieval system provides for significantly different/improved outcomes for patient pain and sample size. PubMed and Cochrane search done for randomized controlled trials that compared the OC method with manual methods was completed. Authors concluded this analysis demonstrates the OC powered system results in less patient pain and a greater amount of biopsy sample capture with similar adverse events. It also demonstrates the OC system is easy to use.

YEAR: 2012

Abrams-Ogg AC, Defarges A, Foster RA, Bienzle D.Comparison of canine core bone marrow biopsies from multiple sites using different techniques and needles.Vet Clin Pathol 2012;41(2):235-42. doi: 10.1111/j.1939-165X.2012.00422.x 119

A pre-clinical study that compared the EZ-IO 15 gauge 25mm needle set and the 13 gauge Jamshidi aspiration/biopsy needle when used to obtain core biopsy specimens in canines.

YEAR: 2011

Berenson JR, Yellin O, Blumenstein B, Bojanower D, Croopnick J, Aboulafia D, et al.Using a powered bone marrow biopsy system results in shorter procedures, causes less residual pain to adult patients, and yields larger specimens.Diagnostic Pathology 2011;6:23 45

This article outlines the 102 patient, multi-center, randomized, controlled trial comparing the powered OnControl system to the standard manual technique in community-based cancer clinics. Thirteen device operators from 10 sites participated. Procedure time was significantly less for the powered device (102.1 ± 86.4 seconds) compared to the manual device (203.1 ± 149.5 seconds; p<0.001). One day following the procedure more patients were pain-free from the powered group (67%) than the manual group (33%); sample volume was larger for the powered group (36.8 mm3 ± 21.2) than the manual group (20.4 mm3 ± 9.0; p=0.039). Conduct of this trial was sponsored by Vidacare Corporation.

Berenson JR, Yellin O, Blumenstein B, Philbeck T.Rotary-powered bone marrow access results in shorter procedure time, larger core specimens and less residual pain for patients.J Vasc and Interv Radiol 2011;22(3):S15 64

This abstract describes the 102 patient, multi-center, trial comparing the powered OnControl system to the standard manual technique. Results showed procedure time was significantly less, more patients were pain free one day following the procedure, and sample volume was larger for the powered group. This trial was sponsored by Vidacare Corporation.

Abstract (Oral Presentation at 2011 SIR)

Cherington C, Robetorye R, Anderson EM et al.High quality bone marrow core biopsy and aspiration (BMBX) procedures can be performed by a nurse led team using the OnControl battery powered bone marrow biopsy system.Blood (ASH Annual Meeting Abstracts)2011;118: Abstract 4743 78

In this clinical study, a nurse-led bone marrow biopsy team evaluated the OnControl system for patient care and safety, team satisfaction and specimen quality. Ninety-four (94) bone marrow biopsy procedures were performed and specimen quality was compared to 25 manual specimens obtained by the same team. Results showed the majority of nurses felt in control of depth, were satisfied with ease of aspirate collection, felt improved ergonomics, and preferred OnControl over the manual if given a choice. All but 2 samples collected with OnControl were adequate for evaluation. The authors concluded that in the hands of experienced individuals, OnControl can consistently yield high-quality bone marrow biopsy specimens.

Higgins, R, Brenner A, Lampkin HT.Characterization of bone marrow core biopsy artifact due to aspiration: implications for technique and specimen quality.Arch Pathol Lab Med 2011;135:1179-80 85

This pre-clinical study sought to characterize aspiration artifact in the bone marrow to determine the distance from the aspirate site at which artifact would not be observed. Bone marrow aspiration of 3ml, 4ml, and 10ml were performed in the iliac crest with biopsy specimens collected in 0.5 cm intervals from the aspiration site. The iliac crest surrounding the 10 ml aspiration site was excised for evaluation. Results showed that none of the collected specimens demonstrated aspiration artifact. When evaluating the excised bone, it was noted that the artifact symmetrically affected an area of 0.4 cm wide and 1.6 cm deep; a calculated 0.2ml defect. This study was sponsored by Vidacare Corporation.

Miller LJ, Philbeck TE, Montez DF et al.Powered bone marrow biopsy procedures produce larger core specimens, with less pain, in less time than with standard manual devices.Hematology Reports 2011;3:e8:22-5. doi:10.4081/hr.2011.e8 90

In this study healthy volunteers were used to comparatively evaluate the powered OnControl system and the standard manual biopsy device. Each subject had a procedures performed with both devices, the order performed was randomized. Results showed samples were obtained in 66.7% of manual procedures and 100% of powered procedures (only single attempts were permitted). Mean time to sample was 86 seconds for the manual group and 47 seconds for the powered; mean second look pain score using 100mm VAS (where higher number indicate greater pain) was 33.3 for the manual and 20.9 for the powered. Pathology evaluation showed a mean sample volume of 11.0 ± 10.8mm^3;for the manual and 49.1 ± 21.5 mm^3 for the powered. This study was sponsored by Vidacare Corporation.

Reed LJ, Raghupathy R, Strakhan M et al.The OnControl bone marrow biopsy technique is superior to the standard manual technique for hematologists-in-training: a prospective, randomized comparison.Hematology Reports 2011;3(e21). doi:10.4081/hr.2011.e21 96

This article describes a 54 patient randomized controlled trial conducted at 2 academic centers comparing the OnControl powered bone marrow system and the standard manual device in a teaching hospital employing hematologists-in-training. The primary endpoint of the study, the mean length of the marrow biopsy specimens, a surrogate for marrow quality, was determined by a pathologist in a blinded manner. It was concluded that bone marrow procedures performed by hematologists-in-training were significantly faster and superior in quality when performed with the powered device compared to manual devices. These data suggest that the powered device may be considered a new standard of care for adult hematology patients. The powered device also appears to be a superior method for training hematology fellows. This study was sponsored by Vidacare Corporation.

Reed, LJ, Raghupathy R, Strakhan, M et al.The powered bone marrow biopsy technique is superior to the standard manual technique for hematologists-in-training: a prospective, randomized comparison.American Society of Hematology (ASH) December 2011; abstract 3133 95

This abstract describes a 54 patient randomized controlled trial conducted at 2 academic centers comparing the OnControl powered bone marrow system and the standard manual device in a teaching hospital employing hematologists-in-training. The primary endpoint of the study, the mean length of the marrow biopsy specimens, a surrogate for marrow quality, was determined by a pathologist in a blinded manner. It was concluded that bone marrow procedures performed by hematologists-in-training were significantly faster and superior in quality when performed with the powered device compared to manual devices. These data suggest that the powered device may be considered a new standard of care for adult hematology patients. The powered device also appears to be a superior method for training hematology fellows. This study was sponsored by Vidacare Corporation.

Swords RT, Anguita J, Higgins RA et al.A prospective randomized study of a rotary powered device (OnControl) for bone marrow aspiration and biopsy.Journal of Clinical Pathology 2011. Doi:10.1136/jclinpath-2011-200047 100

Two large academic centers participated in this prospective randomized study comparing use of the manual bone marrow biopsy device to the powered OnControl bone marrow biopsy system for collection of bone marrow biopsy specimens in adult patients. Fifty patients were enrolled into this study, 25 were assigned to the manual group and 25 were assigned to the powered group. The powered system was superior to the manual device with respect to patient perceived pain from needle insertion and procedural time. Blinded pathological evaluation indicated that specimens collected with the powered system were longer and wider than those collected with the manual device. Authors concluded that the superior size and overall quality of the specimens retrieved using the powered system provide more material for pathologic evaluation, thereby increasing diagnostic yield and reducing the need for repeat procedures.

Wilkins BS.Pitfalls in bone marrow pathology: avoiding errors in bone marrow trephine biopsy diagnosis.J Clin Pathol 2011.doi:10.1136/jcp.2010.080838 58

Description of steps necessary and common errors to avoid for correct reporting of bone marrow trephine specimens.

YEAR: 2010

Berenson J, Yellin O, Bojanower D et al.A multicenter randomized clinical trial comparing a powered bone marrow biopsy system and manual bone marrow biopsy procedures.Blood 2010;116(21):1571 4

This abstract describes a 102-patient multicenter randomized clinical trial that was designed to determine if a new powered bone marrow sampling device has advantages over traditional manually-inserted needles in terms of decreased pain, decreased procedure time, higher biopsy core capture rate, ease of use, improved sample yield, and higher operator satisfaction scores. Results suggest use of the powered bone marrow biopsy device markedly shortens the procedure time and reduces intermediate-term pain—important considerations for the quality of life for patients undergoing this procedure.

Abstract

Miller L, Philbeck T, Montez D et al.Comparing powered bone marrow biopsy procedures to manual bone marrow biopsy procedures using healthy volunteers.Blood 2010;116(21):648 2

This abstract describes a 24-subject/48-biopsy specimen study designed to determine if the powered bone-marrow biopsy device has advantages over traditional manual devices in terms of decreased pain, insertion time, and improved sample yield. Results suggest the superior size and overall quality of core specimens delivered by the powered device may provide more material for pathological evaluation of hematopoietic and oncological disorders. The powered device was significantly faster in obtaining a biopsy than the manual device and its capture rate in obtaining a satisfactory sample was much higher. Use of the powered device significantly decreases overall procedure pain.

Musolino A, Guazzi A, Nizzoli R, Panebianco M, Mancini C, Ardizzoni A.Accuracy and relative value of bone marrow aspiration in the detection of lymphoid infiltration in non-Hodgkin lymphoma.Tumori 2010;96:24-7. 52

This article evaluates the correlation between bone marrow aspirate and biopsy results in 51 patients with NHL that received both procedures simultaneously. They found that the agreement level was 80% for this patient population, with discrepancies in 20% of cases evaluated.

Swords A, Anguita J, Higgins RA et al.A new rotary powered device for bone marrow aspiration and biopsy yields superior specimens with less pain: results of a randomized clinical study.Blood 2010;116(21):650-1 3

This abstract describes a 50-patient study that compared the powered device to the traditional manual technique by relatively assessing pain scores, procedure times, biopsy capture rates, quality of material retrieved, safety and operator satisfaction. Results suggest that the use of a powered bone marrow biopsy device significantly reduces needle insertion pain. Moreover, the superior size and overall quality of core specimens retrieved by the powered device provides more material for pathologic evaluation, thereby increasing diagnostic yield and reducing the need for repeat procedures. This study was sponsored by Vidacare Corporation.

Swords RT, Kelly KR, Cohen SC et al.Rotary powered device for bone marrow aspiration and biopsy yields excellent specimens quickly and efficiently. J Clin Pathol 2010;63:562-5 6

This article summarizes a preclinical study designed to determine cellular artifact or thermal damage resulting from powered bone marrow sampling and a clinical evaluation of the powered bone marrow sampling device. No cellular artifact or thermal damage was found and the device was found to be safe and easy to use, with significantly shorter procedure time than when using a manual technique.

YEAR: 2009

Brenner A, Miller L, Philbeck T, Hacker S.Bone marrow sampling using a rotary powered device yields excellent biopsy specimens in an animal model.Haematologica 2009; 94(s2) 76

This pre-clinical study evaluated the quality and length of bone marrow core biopsy samples acquired using the powered OnControl device and the standard manual device. Thirty-three samples were collected. An interim pathology report of 13 samples (8 powered; 5 manual) indicated no cellular damage or other significant artifact for either device. The mean length of sample for the powered group was 22.2 ± 10.8mm; the mean length of sample for the manual group was 12.7 ± 6.8mm. This study was sponsored by Vidacare Corporation.

YEAR: 2008

Abla O, Friedman J, Doyle J.Performing bone marrow aspiration and biopsy in children: Recommended guidelines.Paediatr Child Health 2008;13(6):499-501 44

This article provides guidelines for the performance of bone marrow aspiration and trephine biopsies in children. It is intended to be useful for both general pediatricians and pediatric hematologists and oncologists. The departmental procedure and guideline document is included in the publication.

Goldberg C, Sacher R, Vergidis D.Bone marrow aspiration and biopsy.Emedicine.medscape.com. http://emedicine.medscape.com/article/207578-print. Updated April 7, 2008 82

This article provides a detailed overview of bone marrow aspiration and biopsy from initial patient visit through processing and reporting.

Hasserjian RP.Reactive versus neoplastic bone marrow.Arch Pathol Lab Med 2008;132:587-94 84

This article provides an overview of how excellent diagnostic samples, appropriate ancillary testing, and knowledge of clinical context provide the pathologist with ability to distinguish between common reactive and neoplastic processes that involve bone marrow.

Hernandez JD, Wesseling K, Pereira R, Gales B, Harrison R, Salusky IB.Technical approach to iliac crest biopsy.Clin J Am Soc Nephrol 2008;3:S164-9. doi:10.2215/CJN.00460107 121

This article provides a general overview of the process of iliac crest bone biopsy including the indications, preparation, instrumentation, and potential complications, with a focus on use of the procedure for diagnosis and treatment of renal osteodystrophy.

Lee SH, Erber WN, Porwit A, Tomonaga M, Peterson LC.ICSH guidelines for the standardization of bone marrow specimens and reports.International Journal of Laboratory Hematology 2008;30:349-64 43

The International Council for Standardization in Hematology (ICSH) formed a Working Party for the standardization of bone marrow specimens and reports to prepare a set of guidelines based on preferred best practices. The guidelines were reviewed by an international panel of experts and addresses the procedure from indications for bone marrow examination to reporting results and storage of specimens.

Welker JA, Henshaw RM, Jelinke J, Shmookler BM, Malawer MM.The percutaneous needle biopsy Is safe and recommended in the diagnosis of musculoskeletal masses. Outcomes analysis of 155 patients at a sarcoma referral center.Cancer 2000;89(12):2677-86 103

The objective of this study was to evaluate percutaneous core needle biopsy in the diagnosis of musculoskeletal sarcomas. One hundred seventy-three biopsy procedures were performed; in 88.2% of cases, a single percutaneous biopsy was adequate. Additionally, patients undergoing percutaneous biopsy rather than open biopsy had lower rates of major diagnostic errors and complications. The authors concluded that percutaneous needle biopsy was found to be extremely effective and safe for the diagnosis of musculoskeletal masses.

YEAR: 2005

Graf BL, Korte W, Schmid L, Schmid U, Cogliatti SB.Impact of aspirate smears and trephine biopsies in routine bone marrow diagnostics: a comparative study of 141 cases.Swiss Med Wkly 2005;135:151-9. 56

Compares the diagnostic impact of bone marrow cytology in combination with flow cytometry analysis of aspirate smears and bone marrow histology together with immunohistochemical examination of trephine biopsies. Diagnoses between aspirate and biopsy were concordant in 80.5% cases.

Naznin M, Wahab AJ, Kalavathy R.A review of bone marrow examinations in Tengku Ampuan Afzan hospital (HTAA), Kuantan.The International Medical Journal 2005;4(1). http://www.eimjm.com/vol4-No1.html 92

This retrospective study evaluated the adequacy of bone marrow aspirate and biopsy samples collected over the course of one year. Of 69 aspirations and 61 biopsies, 42% of aspirations and 32% of biopsies were found to be inadequate. The authors conclude that aspirate and biopsy samples are complementary and give a higher diagnostic yield when both are available for a patient.

YEAR: 2003

Campbell JK, Matthews JP, Seymour JF, Wolf MM, Juneja SK.Optimum trephine length in the assessment of bone marrow involvement in patients with diffuse large cell lymphoma.Annals of Oncology 2003;14:273-6 60

Evaluation of the relationship between length of trephine sample and the number of positive cases, in 172 patients with diffuse large cell lymphoma (DLCL). Found that likelihood of positive diagnosis was related to trephine length with no additional benefit noted for bilateral biopsies; examining serial biopsy sections from a single side can provide sufficient diagnostic information.

YEAR: 2002

Jelinek JS, Murphey MD, Welker JA et al.Diagnosis of primary bone tumors with image-guided percutaneous biopsy: experience with 110 tumors.Radiology 2002;223(3):737-7 88

One hundred ten consecutive primary bone tumor biopsies were performed with CT or fluoroscopy guidance. The authors present the results of the collected biopsies

Nanda A, Basu S, Marwaha N.Bone marrow trephine biopsy as an adjunct to bone marrow aspiration.J Assoc Physicians India 2002;50:893-5 91

The objective of this study was to evaluate the efficacy of bone marrow aspiration as compared to bone marrow biopsy for the purpose of disease diagnosis. Of 420 consecutive cases, aspiration alone was sufficient in making a diagnosis in 372 (88.6%). In the remaining cases bilateral biopsy was required to reach a diagnosis.

YEAR: 2000

Saifuddin A, Mitchell R, Burnett SJD, Sandison A, Pringle JAS.Utltrasound-guided needle biopsy of primary bone tumours.J Bone Joint Surg Br 2000;82-B(1):50-4 99

This study evaluated use of ultrasound guided Trucut needle biopsy in 63 patients with suspected primary bone tumors. Results showed the diagnostic accuracy of US guided biopsy was 98.4% as compared to surgical biopsy. The authors concluded that on a selected group of patients, ultrasound is a reliable technique of guidance for percutaneous needle biopsy of bone tumors.

YEAR: 1999

Cheson BD, Horning SJ, Coiffier B, Shipp MA, Fisher RI, Connors JM, et al.Report of an international workshop to standardize response criteria for Non-Hodgkin's Lymphomas.J Clin Oncol 1999;17(4):1244-53 65

In an attempt to develop standardization among clinicians, lymphoma investigators from NCI formed cooperative groups and established a consensus on a standardized set of guidelines for response assessment in adult patients with indolent and aggressive NHL. This document was subsequently reviewed and approved by European lymphoma experts.

Reid MM, Roald B.Deterioration in performance in obtaining bone marrow trephine biopsy cores from children.J Clin Pathol 1999;52;851-2 122

This article describes a follow up study to a prior study conducted by the same group of investigators (Reid 1996) evaluating the adequacy of bone marrow biopsy specimens obtained from children. Specimens obtained from 25 different centers were evaluated by a central pathologist and graded for adequacy. Of 605 specimens collected from 150 children with neuroblastoma, 154 specimens (25%) were deemed inadequate. The authors concluded that local initiatives involving active and direct feedback from reporting pathologists should be employed to influence operators.

UK

YEAR: 1996

Reid MM, Roald B.Adequacy of bone marrow trephine biopsy specimens in children. J Clin Pathol 1996;49:226-9 57

Evaluation of 822 biopsy specimens for adequacy, collected from children with neuroblastoma over five years, from 25 centers. Found that 17% of biopsy specimens collected were inadequate.

YEAR: 1995

Howard MR, Taylor PRA, Lucraft HH, Taylor MJ, Proctor SJ.Bone marrow examination in newly diagnosed Hodgkin's disease: current practice in the United Kingdom.British J of Cancer 1995;71:210-2 61

Results of a questionnaire study sent to UK hematologists and oncologists shows that hematologists were significantly more likely to perform routine bone marrow examination in all patients, including newly diagnosed Hodgkin's patients, than oncologists. This suggests that many patients are undergoing an invasive procedure with minimal chance of the results influencing their management.

YEAR: 1992

Bishop PW, McNally K, Harris M.Audit of bone marrow trephines..Journal of Clinical Pathology 1992;45:1105-8. 50

This article describes an evaluation of 767 trephines performed at The Christie Hospital, Manchester from June 1, 1990- May 31, 1991, to establish criteria for adequacy for bone marrow trephine biopsy specimens and audit institutional performance.

Winfield DA, Polacarz, SV.Bone marrow histology 3: Value of bone marrow core biopsy in acute leukemia, myelodysplastic syndromes, and chronic myeloid leukemia.Journal of Clinical Pathology 1992;45:855-9 42

This article examines the role bone marrow aspirate and core biopsy play in diagnosis and regular monitoring of acute myeloblastic leukemia (AML), megakaryoblastic leukaemia and acute myelofibrosis, acute lymphoblastic leukemia (ALL), myelodysplastic syndromes (MDS), and chronic myeloid leukemia (CML). The authors conclude that a core biopsy specimen complements the peripheral blood and marrow aspirate findings in providing additional information for the diagnosis and assessment of prognosis.

YEAR: 1989

Morra E, Lazzarino M, Castello A, DInverardi D, Coci A, Pagnucco G.Bone marrow and blood involvement by non-Hodgkin's lymphoma: A study of clinicopathologic correlations and prognostic significance in relationship to the working formulation.Eur J Haematol 1989;42:445-53 67

The objective of this study was to determine the clinicopathologic correlations and impact on survival of bone marrow and peripheral blood involvement in a series of 172 cases of NHL. Results showed that the overall incidence of blood involvement by lymphoma was 28.5%; blood involvement correlated with splenomegaly, bulky disease, advance clinical stage, and extent of bone marrow infiltration.

Pileri S, Poggi S, Baglioni P, Montanari M, Sabattini E, Galieni P, et al.Histology and immunohistology of bone marrow biopsy in multiple myeloma.Eur J Haematol Suppl 1989;51:52-9 53

Fixed biopsy samples from 125 multiple myeloma patients were reviewed according to morphological and immunohistological criteria. Comparison of the findings of biopsies and aspirates, the aspirate sample lead to an underestimation of the tumor burden in 30% of cases.

Abstract

YEAR: 1986

Beckstead JH.The bone marrow biopsy. A diagnostic strategy.Arch Pathol Lab Med 1986;110(3):175-9 75

This article discusses the "optimal use" of bone marrow biopsy as a tool in the evaluation of human bone marrow in light of technical advances improving the diagnostic information available from properly prepared bone marrow specimens. Details on diagnosing specific diseases is also included.

YEAR: 1985

Ginaldi S, Williams CD.Seeding of malignant lymphoma along the tract after bone marrow biopsy.South Med J 1985;78(8):1007-8 81

In this case report, a 74 year-old man received a bone marrow biopsy for evaluation of non-Hodgkin's lymphoma. Within approximately 1 year of the bone marrow biopsy the patient was found to have developed a 6 cm tumor at the original biopsy site as a result of suspected seeding along the needle tract.

YEAR: 1984

Koepke JA.Examination of the bone marrow.Laboratory Hematology 1984:1023-50 101

This article provides an overview of bone marrow examination from indication through processing and final report.

YEAR: 1983

Faugere MC, Malluche HH.Comparison of different bone-biopsy techniques for qualitative and quantitative diagnosis of metabolic bone diseases.J Bone Joint Surg Am 1983;65:1314-8 46

This study compared bone biopsy samples taken using a 3mm diameter Jamshidi needle and 5mm diameter electric drill for qualitative and quantitative study of bone histology. Statistical evaluation of the differences and correlations between histomorphometic parameters was performed; results showed that 3mm diameter samples were sufficient for qualitative diagnosis but were not optimum for the quantitative evaluation of cellular parameters of resorption and formation.

YEAR: 1982

Bartl R, Frisch B, Burkhardt R, Gettner G, Mahl G, Fateh-Moghadam A, et al.Assessment of bone marrow histology in the malignant lymphomas (non-Hodgkin's): correlation with clinical factors for diagnosis, prognosis, classification and staging.Brit J of Haematol 1982;51:511-30 66

A retrospective evaluation of bone marrow biopsies from 678 untreated patients with established malignant NHL to determine the incidence of bone marrow involvement, test independent prognostic relevance of marrow histology, classify bone marrow findings using Lennert's classification, and analyze the mode of spread of malignant lymphoma in marrow to determine staging criteria.

YEAR: 1978

Byrnes RK, McKenna RW, Sundberg RD.Bone marrow aspiration and trephine biopsy. An approach to a thorough study.Am J Clin Pathol 1978;70(5):753-9 77

This article describes the relationship between multiple studies performed on bone marrow specimens for the purpose of reaching a correct diagnosis. The authors concluded that utilization of biopsy material by the methods described in the article will provide complete, accurate and reproducible information and minimize the necessity for repeating a biopsy for morphologic diagnosis or ancillary studies.

YEAR: 1976

Garrett TJ, Gee TS, Lieberman PH, McKenzie S, Clarkson BD.The role of bone marrow aspiration and biopsy in detecting marrow involvement by nonhematologic malignancies.Cancer 1976;38(6):2401-3 51

This abstract describes the review of records at memorial Sloan-Kettering Cancer Center evaluating biopsy and aspirate testing. Supports both aspiration and biopsy are indicated for full evaluation of bone marrow in cancer patients.

Abstract

YEAR: 1974

Bearden JD, Ratkin GA, Coltman CA.Comparison of the diagnostic value of bone marrow biopsy and bone marrow aspiration in neoplastic disease.J Clin Pathol 1974;27:738-40 59

Evaluation of 205 simultaneously collected bone marrow biopsy and aspirate specimens from patients with lymphoma, leukemia, and a variety of solid tumors. Specimens were evaluated for adequacy, number of positive biopsies, and disparity between biopsy and aspirate.