

Bibliography

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

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.

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.

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.

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Bibliography

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.

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 ($36.8 \text{ mm}^3 \pm 21.2$) than the manual group ($20.4 \text{ mm}^3 \pm 9.0$; $p = 0.039$). 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.

Bibliography

- 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.
- Abstract (Oral Presentation at 2011 SIR)*
- 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 $11.0 \pm 10.8 \text{ mm}^3$; for the manual and $49.1 \pm 21.5 \text{ mm}^3$ 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.

YEAR: 2010

Bibliography

- 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*
- 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**

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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.