
In this clinical trial, 26 subjects underwent bilateral bone marrow biopsy procedures performed using the Powered device on one side and the Manual device on the other. Results showed samples were obtained in 66.7 % of Manual procedures and 100 % of Powered procedures. Mean procedure time through core ejection was 86 seconds for the Manual device and 47 seconds for the Powered; mean second look overall pain score using 100mm VAS (where higher numbers indicate greater pain) was 33.3 for the Manual and 20.9 for the Powered procedures. Pathology assessment showed a mean sample volume of 11.0 ± 10.8 mm³ for the Manual and 49.1 ± 21.5 mm³ for the Powered. This study was sponsored by Vidacare Corporation.


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.

Berenson JR, Yellin O, Blumenstein B, 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.

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). This study was sponsored by Vidacare Corporation.


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. This study was sponsored by Vidacare Corporation.

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.

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


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.


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.
COMPLICATIONS


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.

DEVICES


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.

PAIN MANAGEMENT


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.


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.

PATHOLOGY


This abstract describes a pre-clinical study conducted to characterize artifact due to aspiration of large volumes of bone marrow and to determine how far core biopsies should be taken from the aspiration site to avoid artifact. Aspirate volumes of 3ml, 4ml, and 10ml were taken from the posterior iliac crest of 2 anesthetized swine; core biopsy samples were taken in 0.5cm intervals from the aspiration sites. The iliac crest surrounding the 10ml aspiration site was excised for evaluation. Results showed a 0.4cm wide and 1.6cm deep defect surrounding the 10ml aspiration site. No aspiration artifact was identified in the biopsy samples collected. The study concludes that obtaining biopsy samples from an area greater than 0.2cm from the aspiration site may be sufficient to overcome the aspiration artifact. (abstract) This study was sponsored by Vidacare Corporation.


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.


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.