Prospective Trial of Bipolar Sealer for Reduction of Intra-Operative Blood Loss in Total Hip Arthroplasty using the Anterior Hip Approach

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INTRODUCTION: Although total hip arthroplasty (THA) via a direct anterior approach (DAA) is considered a popular procedure, it has a significant learning curve and potential complications, namely intraoperative hemostasis. The bipolar tissue sealer (Werewolf Fastseal 6.0 Bipolar Tissue Sealer; Smith & Nephew) aims to mitigate this issue. The objective of this prospective pilot clinical trial was to evaluate how this device can decrease blood loss intraoperatively via a direct anterior approach in ambulatory surgery centers and hospital settings. The primary endpoint of change in hemoglobin from the pre-operative phase to the post operative phase (48-72 hours) was analyzed.

METHODS: A pilot prospective trial of 75 patients was conducted and analyzed in a control group based on recent historical data of the principal investigator's clinical practice utilizing standard electrocautery only. All 75 patients were scheduled to receive the intervention of having a bipolar tissue sealer available for hemostasis during surgery. Follow-up for all participants was conducted 6 weeks after surgery. Demographic data, pain control via a visual analog scale, and drug usage, along with a comparison of the Harris Hip Score (preoperative phase and at 6 weeks post-operation) for functional outcomes were collected and analyzed. Operative time, complications, and length of hospital stay were also recorded. Statistical comparisons of the primary objectives were performed using the t-test for significance.

RESULTS: 75 patients were prospectively consented and underwent a DAA THA with the Fastseal bipolar tissue sealer with 4 patients who declined participation after the procedure. This left 71 patients which were compared to 23 patients from our historical data set with similar DAA THA and available post-operative hemoglobin data. For our primary endpoint, we noted a mean decrease in hemoglobin of 2.06 g/dL while utilizing the bipolar tissue sealer compared to historical data, utilizing standard electrocautery only, showing a mean decrease of 2.8 g/dL with a p-value of 0.0037. There was no significant difference in the operative time with the use of the device (p-value of 00.75). Most patients were discharged the same day, with no reoperation needed for wound complications at 6 weeks postoperatively.

DISCUSSION: This pilot trial showed that the bipolar tissue sealer significantly reduced blood loss during a total hip arthroplasty with a direct anterior approach when compared to standard electrocautery, while also not significantly lengthening operative times. In addition, most patients were discharged on the same day, and no wound complications were observed in the 6-week post-operative period. Although further studies are needed, and there are limitations to this trial, the authors feel that this device offers an appealing option for surgical hemostasis in the total hip arthroplasty performed using a direct anterior approach, even in an ambulatory surgery setting.

CLINICAL SIGNIFICANCE: Control of hemostasis during a total hip arthroplasty utilizing a direct anterior approach with a post-operative plan of same-day discharge is clinically significant. This has a significant impact on patient outcomes and return to functionality along with decreased overall utilization of healthcare resources and subsequent overall costs.

Table 1. Demographic Data

	Control Group Data (n = 23)	Interventional Group Data (n=75)
Average Age (years)	67.35(48-77)	71 (36-80)
Male (n/(%))	12 (55%)	38 (51.3%)
Female (n/(%))	10 (45%)	36 (48.6%)
Pre-Operative Hemoglobin (g/dL)	14.19	13.9
Pre-Operative Risk Stratification Score	27.14 (5-70)	16 (0-100)
Hemoglobin A1C	6.1 (5.1-7.7)	5.7 (4.9-7.8)
BMI	30.15 (21-38)	29.4 (19-40)
Harris	47.6	47.68

Table 2. Operative/Post-Operative Data Analysis

	Control Group Data	Interventional Group Data	P value
Change in Hgb (g/dL)	2.8	2.06	0.0037
Operative Times (m)	50.5	47.95 (34-69)	0.75