

Hemostasis With a Bipolar Sealer During Surgical Correction of Adolescent Idiopathic Scoliosis

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Study Design: Retrospective before-after comparison study.

Objective: The primary aim of this study was to evaluate the effectiveness of a radiofrequency-based bipolar hemostatic sealer during surgical correction of adolescent idiopathic scoliosis (AIS).

Summary of Background Data: Spinal reconstructive surgery is commonly associated with excessive blood loss. Perioperative bleeding is of particular concern during correction of AIS, which often requires allogeneic or autologous transfusion. However, there are specific risks and limitations that often preclude the utilization of transfusions. Alternatives include the use of antifibrinolytic drugs and topical fibrin-based and thrombin-based agents, although safety and effectiveness are yet to be fully established. There is a clear need for assessing alternative methods of hemostasis.

Methods: One hundred seventy-six AIS patients undergoing corrective spinal surgery were included in this study. Seventy-six consecutive patients were treated intraoperatively with a standard method of hemostasis consisting of hypotensive anesthesia, thrombin-soaked sponges, and intraoperative blood salvage (Control). Subsequently, an additional 100 consecutive patients were treated after the introduction of a bipolar sealer (Aquamantys 2.3 Bipolar Sealer, Salient Surgical Technologies, Portsmouth, NH). The outcomes of this study were estimated blood loss (total and per level) and transfusion rate.

Results: Blood loss was reduced by 57% after the introduction of the bipolar sealer compared with the Control (bipolar sealer: 435 ± 192 mL, Control: 1009 ± 392 mL; $P < 0.001$). There was a statistically significant difference between groups for blood loss per fusion level (bipolar sealer: 39 ± 17 mL, Control: 95 ± 33 mL; $P < 0.001$). Five (6.6%) Control patients required blood transfusions versus none treated with the bipolar sealer ($P = 0.014$). Complication rates were similar between the groups.

Conclusions: These findings suggest that the Aquamantys 2.3 bipolar sealer effectively supports hemostasis and reduces the need for transfusions during surgical correction of AIS.

Key Words: hemostasis, scoliosis, spinal corrective surgery, bipolar sealer

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Spinal corrective surgery is commonly associated with excessive blood loss, known to increase the rate of surgical complications and adverse events, and compromise clinical outcomes.^{1–5} Efforts to control perioperative bleeding have grown with the adoption of advanced surgical techniques and instrumentation, which have increased the potential for blood loss by allowing correction of complex deformity across multiple vertebral levels.^{1,6–9}

Blood loss is of particular concern during the correction of adolescent idiopathic scoliosis (AIS), where excessive bleeding is the second most common surgical complication.^{7,8} This is likely caused by wide surgical exposure encompassing numerous vertebral levels, significant platelet dysfunction, attenuated vasoconstrictive response, protracted intraoperative bleeding time, and increased fibrinolysis during surgery.^{3,10,11} Moreover, profuse intraoperative and postoperative bleeding in these patients commonly necessitates allogeneic or autologous transfusion.^{3,6,9,12} It is accepted that use of allogeneic transfusion should be minimized, as patients often experience increased risk of postoperative infection, higher rates of perioperative blood loss, compromised immune function, reduced coagulation, and longer hospital stay.^{6,9,13,14} Although autologous transfusion does reduce infection risk, factors including limited venous access, preexisting medical conditions, required regeneration time, and low preoperative hematocrit levels can greatly limit its efficacy.^{3,15–19} Alternative methods of red blood cell augmentation, including erythropoietin administration, intraoperative hemodilution, and cell salvage have been used, but high expense and clinical risks preclude their widespread utilization.^{1,9,20,21}

Allowing surgeons to achieve hemostasis rapidly maintains visualization of the surgical field, minimizes surgical error and operative time, and effectively reduces postoperative patient morbidity.^{2,22} Standard operative

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techniques for achieving hemostasis include application of manual pressure, suture ligation, and electrocautery.^{2,3} However, complex spinal reconstruction surgery such as in AIS often requires highly invasive dissection and prolonged operative times.^{2,9,23} The resulting excessive bleeding originating from large surface areas of exposed tissue necessitates alternative, more effective hemostatic methods.^{2,24,25}

Antifibrinolytic drugs including aprotinin, tranexamic acid, and aminocaproic acid have demonstrated some success in reducing perioperative blood loss.³ Topical thrombin coagulants have also been widely used.² However, the safety of some of these hemostatic agents has been questioned.^{2,3,6,26,27} Moreover, the ability of these methods to effectively and consistently reduce transfusion rates remains unclear.^{2,3} There is a clear need for assessing alternative methods of perioperative blood loss control. The purpose of this study was to evaluate the hemostatic effectiveness of a bipolar sealer during corrective surgery for AIS.

MATERIALS AND METHODS

Patients

One hundred seventy-six patients undergoing corrective spinal surgery for AIS were included in this study. Patients presented with idiopathic spinal deformities in the absence of underlying syndromes or significant comorbidity. Patients with neuromuscular diagnoses (eg, cerebral palsy, myelodysplasia) were excluded from the study.

Seventy-six consecutive patients (65 female; mean age: 14.3 ± 2.0 y) were treated intraoperatively with standard methods of hemostasis consisting of hypotensive anesthesia and operative site packing with thrombin-soaked sponges, and intraoperative blood salvage (Cell Saver). Electrocautery was used to treat areas of spot bleeding. The next 100 consecutive patients (85 female; mean age: 15.1 ± 2.5 y) underwent an identical regimen with the exception of receiving hemostatic treatment with a bipolar sealer (Aquamantys 2.3 Bipolar Sealer, Salient Surgical Technologies, Portsmouth, NH). This device (Fig. 1) delivers radiofrequency energy to bleeding tissues using a conductive saline fluid that increases the affected surface area during hemostasis, and maintains a relatively cool surface temperature of approximately 100°C .²⁸ The thermal effect of the radiofrequency energy shrinks type I and type III collagen fibers in the walls of arteries and veins, which serves as the mechanism to minimize perioperative bleeding.²⁸ Full surgeon control of saline flow is maintained by an electronic switch.

Surgical Intervention

All surgeries were performed by the same surgeon (K.P.M.). Generally, the Aquamantys device was used to treat large areas of muscle or deep fascia, such as the strap muscles after initial stripping. The device was also used around the transverse processes within the muscle and ligament complexes. The facet joints of the thoracic spine



FIGURE 1. Aquamantys RF bipolar sealer device (Salient Surgical Technologies, Portsmouth, NH).

were pretreated. The device was also used on cut portions of the bone during facetectomy before pedicle screw insertion. The device was typically used using a circular motion or slow back and forth passes over the treated tissue with the handpiece deployed for no more than 5 to 10 seconds in any specific spot. For treatment of bone, the device was held in place for 15 to 20 seconds depending on the type of bleeding. For a typical 15 inch exposure the treatment took approximately 5 minutes per side. A large wand was used at a setting of 170 watts and medium flow for treatment of larger areas. A smaller wand set at 130 watts or 150 watts and low flow was used for treatment of smaller areas. The device was not used before exposure of the linea alba and stripping of the periosteum. Steady but not excessive pressure was used in maintaining contact with the treated tissue.

Depending on the conformation and degree of scoliosis, multiple spinal levels from T4 to L3 were instrumented using standard spinal constructs, decortication, and facetectomy for grafting. Initially, apical sublaminar cables were used; however, a switch to polyester bands and clamps was made in the latter half of the Aquamantys group. Patients treated with the bipolar sealer were fused across a mean of 11.1 ± 2.0 levels versus 10.6 ± 1.6 levels for the hemostatic control ($P = 0.08$). Allograft bone substitute and platelet rich plasma or bone marrow aspirate were used during all cases. Lumbar pedicle screws were placed segmentally into the vertebral body to achieve fixation of rod instrumentation, whereas hooks and cables were placed in the thoracic spine.

Intraoperative estimated blood loss (EBL) was derived from cell saver, and from estimates of sponge and irrigation fluid. All estimates were calculated by a transfusion technician and confirmed by the surgeon (K.P.M.) and anesthesia team. Intraoperative and postoperative transfusion need was recorded for all cases. All transfusions occurred as a result of symptomatic need, as opposed to set triggers.

Retrospective chart review was initiated after institutional review board approval (WakeMed Health & Hospitals).

Statistical Analyses

Fisher exact test was used to analyze categorical variables between groups. Independent *t* test was used for comparisons of continuous variables. All values are reported as mean \pm SD.

RESULTS

Patients treated with the bipolar sealer were, on average, almost 1 year older than controls (15.1 vs. 14.3 y, $P = 0.02$). Total EBL for the bipolar sealer group was 57% lower compared with the Control group (bipolar sealer: 435 ± 192 mL, Control: 1009 ± 392 mL; $P < 0.001$; Fig. 2). This reduction was observed despite a slightly larger mean number of operative levels in the bipolar sealer group; 11.13 ± 2.03 versus 10.63 ± 1.6 ($P = 0.08$).

There was also a 59% reduction ($P < 0.001$) in EBL per fusion level in the bipolar sealer group (39 ± 17 mL) versus Controls (95 ± 33 mL; Fig. 3). The reductions in EBL (total and per level) with the bipolar sealer were maintained when controlling for patient age. Five (6.6%) blood transfusions were required in the Control group versus none in the group treated with the bipolar sealer ($P = 0.014$).

Complication rates were similar between the groups. The bipolar sealer group had 2 (2.0%) deep infections and 2 (2.0%) wound dehiscences/delayed skin healing. The Control group had 1 (1.3%) deep infection and 2 (2.6%) wound dehiscences/delayed healing. No patient had clinical nonunion or hardware disruption.

DISCUSSION

Excessive blood loss during surgical correction of idiopathic scoliosis often results in increased surgical complications and adverse events.¹⁻⁵ As a result, many patients experience worse clinical outcomes and increased postoperative morbidity.^{2,22} Thus, it is critical for hemostasis to be achieved as quickly as possible. The current findings suggest that treatment with a bipolar sealer can effectively reduce intraoperative blood loss and the need for transfusion during surgical correction for AIS. These results corroborate and extend previous studies reporting the successful utilization of this technology during liver transplantation and resection, nephrectomy, cholecystectomy, splenectomy, oncology, and orthopaedic joint reconstruction.²⁸⁻³²

The outcomes of this study compare favorably with the results of other hemostatic agents reported in the literature. Tzortzopoulou et al³ performed a systematic safety and efficacy review of antifibrinolytic drug administration after adolescent scoliosis corrective surgery. They identified 6 studies reporting the outcomes for 254 correction cases. Aprotinin, tranexamic acid, and aminocaproic acid were each evaluated in 2 of these studies. Results of this review demonstrated an average decrease

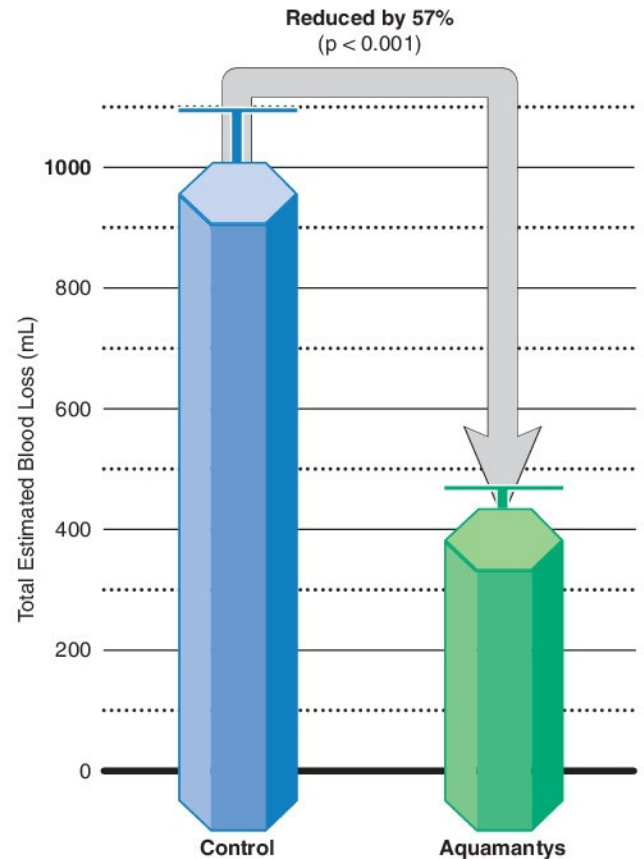


FIGURE 2. Total estimated intraoperative blood loss (mean \pm 95% confidence interval) for 176 patients treated consecutively before ($n=76$) and after ($n=100$) the introduction of the bipolar sealer.

in intraoperative blood loss and in the amount of transfused blood of 427 and 327 mL, respectively. There was no observed difference in the effectiveness across drugs and transfusion requirements did not differ statistically between patients receiving antifibrinolytic or placebo treatment. Although this evidence does suggest that antifibrinolytics are effective hemostatic agents, these drugs may not be cost effective for all cases.^{9,33} Further, the clinical safety of some antifibrinolytic drugs remains a concern. Specifically, aprotinin administration has been associated with increased risk of anaphylaxis, stroke, end-organ damage, and death.^{1,27,34}

Topical hemostatic agents have been widely used in conjunction with standard operative techniques.² These products typically include gelatin, cellulose, synthetic, or glutaraldehyde-based matrices combined with a coagulating agent, typically thrombin.^{2,26,35} Renkens et al²² compared a gelatin sponge-thrombin hemostat with a gelatin-based matrix and thrombin solution in spinal surgery. Within 10 minutes of application, 90% and 98% of patients achieved hemostasis, respectively. EBL during laminectomy with fusion was 475 and 500 mL, respectively. It must be noted that the effectiveness of these hemostatic interventions during correction of idiopathic scoliosis deformity has not

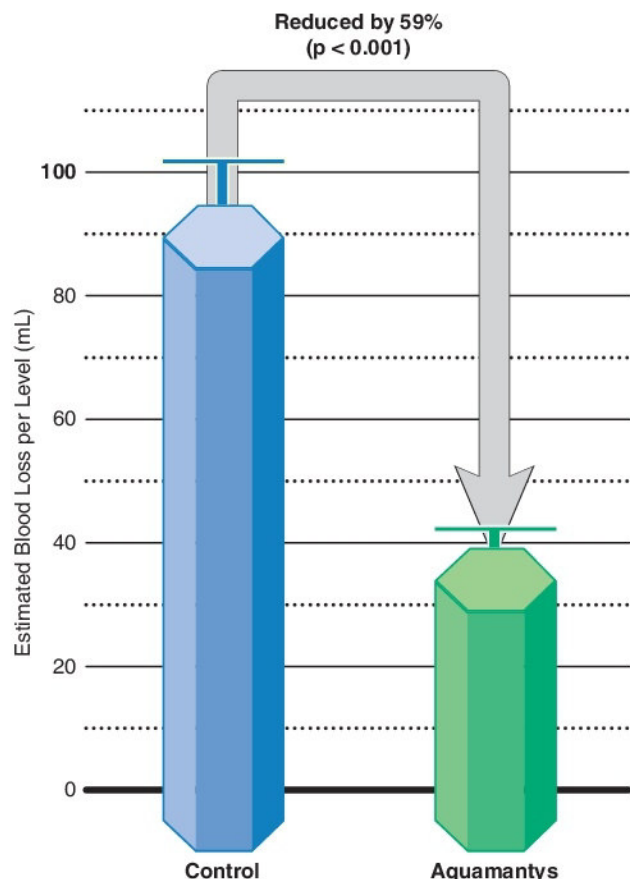


FIGURE 3. Estimated intraoperative blood loss per fusion level (mean \pm 95% confidence interval) for 176 patients treated consecutively before ($n=76$) and after ($n=100$) the introduction of the bipolar sealer.

been established. Moreover, there are concerns regarding potential pathogen transmission and adverse immunologic response. Approximately 1 million surgical procedures are performed in the United States annually using bovine-derived thrombin (bThrombin).^{2,24,26,36} Transmission risk of bovine pathogens has been associated with bThrombin.^{2,26} Moreover, 20% of patients treated with bThrombin develop antibodies that target endogenous thrombin, potentially impairing the patients coagulation response.^{24,26,35,36} Recently, recombinant human thrombin has been introduced as an alternative to bThrombin, although clinical trials are needed to evaluate its effectiveness during complex spinal reconstruction.²

In the absence of a randomized study design, the results of this study may be biased. Thus, potentially important background factors that may be associated with blood loss were not randomly distributed between groups and this could have accounted for a portion of the reported differences in EBL. Nonetheless, the overall reduction in EBL of 57% in the bipolar sealer group was quite robust compared with the control group using thrombin-soaked sponges and this improvement was maintained when the data were analyzed on a per level basis.

In summary, introduction of a bipolar sealer resulted in significant reductions in EBL overall and by fusion level compared with previously used hemostatic measures during AIS corrective surgery. Utilization of a bipolar sealer during correction of idiopathic scoliosis may offer comparable hemostatic effects, without prohibitive cost or adverse drug-related risks. Furthermore, no patient treated with the bipolar sealer required transfusion. The intraoperative hemostatic success of this technology may translate to decreased complications and reduced postoperative patient morbidity.

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