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Efficacy and cost effectiveness of harmonic scalpel compared with electrocautery in posterior instrumentation of the spine

Received: 12 January 2004
Accepted: 19 July 2004
Published online: 15 February 2005
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Abstract Different methods to reduce blood loss during spinal surgery have been described already. Although the use of the harmonic scalpel (HS), an ultrasonically activated coagulator, has been described in endoscopic spinal surgery, its efficacy in posterior instrumentation of the spine remains unclear. The aim of this study was to determine if blood loss was lower using the HS than electrocauterization (EC) and to evaluate the cost effectiveness of the HS in reducing the need for transfusion in patients undergoing posterior instrumentation of the spine. The two groups were matched in a blinded manner, without knowledge of blood loss and were similar with respect to mean age, diagnosis and operation data. All instrumentations were done by the same surgeon. After matching was completed (HS group $n = 50$, EC group $n = 50$) blood loss and overall costs for blood products were

analyzed by independent observers. The following were significantly lower with the HS than with EC: (1) blood loss (1106 ± 985 ml vs 2176 ± 1764 ml, $P < 0.001$), (2) frequency of cell saver use (13 vs 28 patients, $P = 0.001$), (3) average cost of blood products (€72 vs €219, $P < 0.001$), (4) predonation of autologous fresh frozen plasma (2.58 ± 2.78 vs 4.5 ± 2.2 U, $P = 0.002$) and red blood cells (0.38 ± 0.75 vs 0.88 ± 1.1 U, $P = 0.009$). The overall costs, including the costs for the HS, remained neutral. The use of the HS in posterior spinal surgery leads to significantly lower blood loss, and less need for and cost of blood products, compared to EC in cases with major anticipated blood loss.

Keywords Transfusion · Harmonic scalpel · Autologous blood · Spinal fusion

Introduction

Due to the inherent risks of homologous blood transfusions, different methods have been established to reduce the need for allogeneic blood transfusion in patients undergoing spinal surgery. These methods include autologous blood predonation [27, 28], controlled hypotensive anesthesia [10], acute normovolemic hemodilution [3, 5], and intraoperative salvage of shed blood (intraoperative autologous transfusion, IAT) [7].

The efficacy of these methods has been analyzed in different studies, and it has been shown that a combination of these methods has significantly reduced exposure to allogeneic blood products. Another way to reduce the need for allogeneic blood transfusion is to reduce the bleeding itself, which is the aim of a growing number of drug therapies such as aprotinin [13], epsilon aminocaproic acid [6], and deamino-D-arginine vasopressin (DDAVP) [1, 9]. In different studies the possibility of eliminating these techniques or using them selectively to

decrease costs while still safely managing the perioperative blood requirements of patients undergoing spinal surgery has been investigated. There is a growing demand for autologous blood provision combined with an increasing need for cost containment, and some authors believe that these demands can be met less expensively and as reliably by merely predonating sufficient autologous blood [27, 28].

To reduce the rising costs of health care, decrease reimbursements to third-party organizations, avoid possible transfusion complications and increase patient comfort, there is a growing desire to reduce the number of transfusions, regardless of the kind of transfusion. The most reliable method to achieve this would seem to be to reduce blood loss during surgery and therefore the need for extensive predonation and transfusion of blood products.

This is the first study in which the harmonic scalpel (HS) has been evaluated to determine whether it is: (1) beneficial in reducing intra- and postoperative blood loss and therefore the need for predonation and transfusion of different blood products, and (2) cost effective compared to electrocauterization (EC) in posterior spinal instrumentation.

Material and methods

The study group (group I) consisted of 50 patients undergoing cervical ($n=15$), thoracic ($n=5$) and lumbar ($n=30$) posterior instrumentation, with or without posterior fusion/decompression, for different diseases using the HS (Ethicon Endo-Surgery, Cincinnati, Ohio) from August 2000 through October 2002. A comparison group (group II) underwent similar surgery using an electrocauterizer from June 1998 through July 2000. The two groups were matched in a blinded manner with regard to age, diagnosis, localization of surgery, levels of instrumentation, levels of fusion, levels of decompression, number of screws used, and duration of surgery, without knowledge of the blood loss until matching was completed. Patients with the diagnosis of infection and tumor disease were excluded from the study. The senior author (M.R.) performed all operations.

In all patients surgery was carried out under general anesthesia, and the patients were monitored by electrocardiography, capnography and pulse oximetry, and by recording rectal temperature and blood pressure. The surgery was performed according to standard cervical, thoracic and lumbar procedures. The patients' back was prepared with a midline incision and the posterior aspect of the spine was exposed thoroughly. Meticulous intraoperative hemostasis and liberal use of packing sponges were followed in all cases. Blood loss was estimated by washing blood-soaked sponges/drapes and measuring

the volume of salvaged blood in a cell saver, or suction container if a cell saver was not used. Postoperative blood loss was measured by means of postoperative drains.

The numbers of autologous blood products predonated preoperatively, hemodilution, the use of an IAT device and the amount of autologous/homologous blood transfused perioperatively and throughout the hospitalization were analyzed by an individual who was not involved with the matching of the patients or with the surgical team. A total of 1–3 U of autologous plasma (300 ml each), plus 0–2 U of red cells (200–250 ml each) was collected in one session.

The costs were compared using an investment calculation. The cost elements were costs of capital (depreciation, imputed interest) and operating costs (personnel, material, maintenance and occupancy costs). The total costs were calculated with the following formulas:

Costs = operating costs (OC) + depreciation + interest

Costs = OC + initial cost/economic life + initial cost/2
× interest rate

The costs for the whole operating team (surgeon, assistant, anesthesiologist, nurses) were considered to be €3.14/min. The cost for the Ultracision Harmonic Scalpel with an estimated economic life of 8 years and imputed interest rate of 5% were also calculated per operation. The costs of the handpiece of the Ultracision instrument (estimated economic life 100 operations), the hand-switching adaptor (estimated economic life 30 operations) and the knife itself (estimated economic life 6 operations) were also considered in the calculation. The calculation was performed by an individual not associated with the surgical team or with the individuals who performed the matching or evaluated the amount of blood products used.

The average costs for different blood products are listed in Table 1. Personnel costs for predonating autologous blood were not taken into consideration.

Table 1 Costs for different blood products (*IAT* intraoperative autologous transfusion, *RBC* red blood cells, *FFP* fresh frozen plasma)

Blood product	Costs (€)
IAT device	72.60 per operation
Homologous RBC	75 per unit (200 ml)
Homologous FFP	60 per unit (300 ml)
Predonated autologous FFP	46.02 per draw ^a
Predonated autologous FFP + RBC	70.05 per draw ^b
Platelets	295 per unit (200 ml)

^a1–3 U FFP was obtained per draw (1 U FFP = 300 ml)

^b1–3 U FFP and 1–2 U RBC were obtained per draw (1 U RBC = 200–250 ml)

Table 2 Patient demographics

	HS group (<i>n</i> = 50)	EC group (<i>n</i> = 50)	<i>P</i>
Sex (<i>n</i>)			
Male	24	21	0.688 ^a
Female	26	29	
Localization of surgery (<i>n</i>)			
Cervical	15	15	–
Thoracic	5	5	–
Lumbar	30	30	–
Age (years)	50.1 ± 15.6	47.4 ± 18.8	0.553 ^b
Instrumentation (level)	2.3 ± 2.2	2.2 ± 1.9	0.731 ^b
Decompression (level)	0.6 ± 1.0	0.6 ± 0.9	0.646 ^b
No. of screws used	5.0 ± 2.7	4.6 ± 2.7	0.782 ^b
Duration of surgery (min)	152 ± 65	170 ± 70	0.027 ^b
Estimated blood loss (ml)			
Intraoperatively	803 ± 758	1,580 ± 1,458	<0.001 ^b
Postoperatively	303 ± 316	596 ± 535	0.001 ^b
Total	1,106 ± 985	2,176 ± 1,764	<0.001 ^b

^aFisher's exact test^bMann-Whitney nonparametric test for independent samples

The statistical analysis was performed with the SPSS statistical software system (v 9.0 for Windows). Continuous variables are expressed as mean ± standard deviation, and categorical variables as total amount. The difference in the continuous variables was assessed using the Mann-Whitney nonparametric test for independent samples and in categorical variables using the Fisher's exact test (two-tailed). All *P* values less than 0.05 were considered significant.

Results

There were no significant differences between the two groups except with regard to duration of surgery (*P* = 0.27) and estimated blood loss (*P* < 0.001) (Table 2).

The diagnoses before surgery were similar in both groups (Table 3). During cervical procedures in both groups autogenic bone grafting was done with the posterior iliac crest. The type and number of screws used

during cervical procedures were as follows: transarticular screws C1–C2: 28 (HS), 6 (EC); pedicle screws 8 (HS), 10 (EC); lateral mass screws 20 (HS), 18 (EC); isthmus screws C2: 0 (HS), 2 (EC); atlas claws 18 (HS), 0 (EC); occiput plate 4 (HS), 3 (EC). Translaminar wiring C1/C2 was performed only in eight patients in the EC group. Thoracic procedures were done with transpedicular screws without exception (HS 40; EC 35). Bone grafting was performed only for the scoliosis patients (one in each group) with posterior iliac crest and allogeneic bone. Lumbar procedures were done using transpedicular screws without exception (HS 154; EC 160), bone grafting was performed only in eight patients during posterior procedures, four in each group with posterior iliac crest. Delayed two-stage procedures with anterior bone grafting were carried out in 52 patients (26 in each group). The patient's position was always the same during cervical, thoracic and lumbar procedures.

The use of the HS resulted in statistically significantly less intraoperative and postoperative blood loss than EC (HS 1106 ± 985 ml, EC 2176 ± 1764 ml; *P* < 0.001; Table 2).

A total of 30 patients in the HS group predonated blood 43 times and 41 patients in the EC group 75 times. This accounts for 0.86 ± 0.93 draws/patient in the HS group and 1.50 ± 1.1 draws/patient in the EC group (*P* = 0.002). Fresh frozen plasma (FFP) was drawn 27 times in the HS group and 36 times in the EC group, and FFP + red blood cells (RBC) was drawn 16 and 38 times, respectively. Therefore, 30 patients in the HS group donated a total of 129 U autologous FFP and 19 U RBC, and 41 patients in the EC group donated a total of 225 U autologous FFP and 44 U autologous RBC (Table 4). Hemodilution was performed in two patients in the HS group and one patient in the EC group.

An IAT was used in 13 and 28 patients in the HS and EC groups returning a total of 6840 ml and 22,510 ml,

Table 3 Diagnosis in relation to study group

	HS (<i>n</i> = 50)	EC (<i>n</i> = 50)
Cervical (<i>n</i> = 15)		
Rheumatic instability	4	4
Dens fracture	6	7
Revision surgery (non-union)	3	2
Spinal stenosis	2	2
Thoracic (<i>n</i> = 5)		
Scoliosis	1	1
Fracture	2	4
Implant failure	2	0
Lumbar (<i>n</i> = 30)		
Spondylolisthesis	9	8
Degenerative pseudolisthesis	8	9
Failed back surgery syndrome	11	9
Revision surgery (non-union)	2	4

Table 4 Treatment data in relation to study group

	HS group (<i>n</i> = 50)	EC group (<i>n</i> = 50)	<i>P</i> value
IAT device used (no. of patients)	13	28	0.004 ^a
IAT return (ml/patient)	137 ± 301	450 ± 606	0.001 ^b
Predonation of FFP (no. of patients)	30	41	0.027 ^a
Predonation of RBC (no. of patients)	11	21	0.053 ^a
No. of draws (per patient)	0.86 ± 0.93	1.50 ± 1.1	0.002 ^b
FFP donated (U/patient)	2.58 ± 2.78	4.5 ± 2.2	0.002 ^b
RBC donated (U/patient)	0.38 ± 0.75	0.88 ± 1.1	0.016 ^b
Cost of blood products (€/operation)	72.07 ± 82.54	219.08 ± 193.25	< 0.001 ^b

^aFisher's exact test^bMann-Whitney nonparametric test for independent samples

respectively (137 ± 301 ml and 450 ± 606 ml per patient, calculation for the whole study group *n* = 50; *P* = 0.001; Table 4).

A total of 30 patients in the HS group predonated autologous FFP of whom 26 (87%) received 103 U autologous FFP intra- or postoperatively, compared to 41 patients in the EC group of whom 33 (80%) received 170 U. Therefore the average amount of transfused autologous FFP in the whole study group (*n* = 50) was 2.06 ± 2.18 for HS and 3.40 ± 2.38 for EC. There was no significant difference between the groups in the number of patients receiving autologous FFP (*P* = 0.153), but there was a significant difference in the number of units given (*P* = 0.003; Table 5).

A total of 11 patients in the HS group predonated autologous RBC of whom 9 (82%) received 16 U autologous RBC intra- or postoperatively, compared to 21 patients in the EC group of whom 17 (81%) received 35 U. Therefore the average amount of transfused autologous RBC in the whole study group was 0.32 ± 0.65 U in the HS group and 0.70 ± 0.87 U in the EC group. There was no significant difference between the groups in the number of patients receiving autologous RBC (*P* = 0.110), but there was a significant difference in the number of units given (*P* = 0.021).

Two patients in the HS group received 3 U of homologous RBC and five patients in the EC group received 16 U. One patient in the HS group received 2 U of homologous FFP and four patients in the EC group received 15 U. There was no significant

difference between the groups in the number of patients receiving homologous FFP or RBC (FFP *P* = 0.362, RBC *P* = 0.436), or in the number of units given (FFP *P* = 0.165, RBC *P* = 0.218). Only seven patients in the EC group received 10 U of platelets. There was a significant difference between the groups in the number of patients receiving platelets (*P* = 0.012) and in the units of platelets transfused (*P* = 0.006; Table 5).

The average costs for blood products were €219.08 ± 193.25 in the EC group and €72.07 ± 82.54 in the HS group per operation. Personnel costs averaged €530.47 in the EC group and €477.28 in the HS group, and expenditure on materials averaged €101.83 per operation in the HS group. The depreciation on the Ultracision HS was calculated as €65.67 and the interest as €13.13 for 50 operations. Therefore, adding the costs of blood products, the total cost per operation was €729.98 with the HS and €749.55 with EC (Table 4).

Discussion

The HS is an ultrasonically activated coagulator which generates less heat and minimal smoke during surgery compared to EC. The lower degree of heat generation causes far less thermal damage to the tissue than regular EC [4, 22]. The outstanding quality of the HS is its ability to coagulate and cut vessels. Although the use of the HS has been described in endoscopic spinal surgery [19], its efficacy in posterior spinal instrumentation remains unclear. This is the first study in which the role that the HS might play in reducing blood loss and therefore the need for and costs of blood products in posterior instrumentation of the spine have been evaluated.

Diagnosis, the surgical technique employed, posterior vs anterior approach, the use of instrumentation, the number of vertebrae fused, the site of autologous bone graft harvest, male vs female, duration of surgery, patient age, hemodilution, and mean arterial pressure have already been reported as factors influencing blood loss [3, 8, 11, 14, 20, 21, 23]. In our study nearly all of these factors were analyzed and were similar in both groups, except for the duration of surgery (Table 2). Moreover, the matching of the patients, the analysis of blood loss/

Table 5 Transfusions

Transfusion	HS group	EC group	<i>P</i> value
Autologous FFP (patients)	26	34	0.153 ^a
Autologous FFP (U)	2.06 ± 2.18	3.40 ± 2.38	0.003 ^b
Autologous RBC (patients)	9	17	0.110 ^a
Autologous RBC (U)	0.32 ± 0.65	0.70 ± 0.87	0.021 ^b
Homologous FFP (patients)	1	4	0.362 ^a
Homologous FFP (U)	0.04 ± 0.28	0.3 ± 1.15	0.165 ^b
Homologous RBC (patients)	2	5	0.436 ^a
Homologous RBC (U)	0.06 ± 0.31	0.32 ± 1.04	0.218 ^b
Platelets (patients)	0	7	0.012 ^a
Platelets (U)	0	0.20 ± 0.54	0.006 ^b

^aFisher's exact test^bMann-Whitney nonparametric test for independent samples

blood products and the costs for the HS and EC groups were done by independent observers not associated with the surgical team. Therefore, the significant decrease in blood loss observed can be attributed mostly to the properties of the HS as mentioned above.

As we gained experience with the use of the HS, the patients operated on with the HS donated significantly less blood before surgery than those in the EC group because of the recognition of decreased blood loss and therefore decreased need for autologous transfusion. The same was true for the IAT device, which was used significantly less frequently than in the EC group. Some authors claim that intraoperative salvage of blood is neither necessary nor cost effective [27, 28]. Siller et al. [27] found that blood requirements for patients who underwent surgery for idiopathic scoliosis can be met less expensively and more reliably by predonation of autologous blood. The addition of an IAT device to preoperative predonation had no benefit on homologous blood exposure. Due to the obvious reduced bleeding, we started to run the device after some indication that losses were going to be high enough to warrant its use.

Due to reduced predonation there was an obvious increase in patient comfort preoperatively, and also reduced personnel costs for the Anesthesiology Department for performing the drawings which was not considered in our calculation. A survey by the College of American Pathologists reflects this problem. They attributed a unit (minute) value of 22.0 for a homologous donation, compared with 89.0 for an autologous donation [12]. From this point of view it is questionable if autologous blood predonation is the most important tool to handle the blood requirements of patients undergoing posterior spinal surgery properly and safely, especially when overall costs are taken into consideration. Therefore, it seems to be more valuable for the patient and the health-care system to have a tool which decreases the blood loss itself to avoid blood transfusion, regardless of which kind of blood. The results of our study confirm that the HS is also a tool which has outstanding importance in managing the blood requirements of patients beside other techniques.

There are two different considerations when considering the significantly different operating times between the groups (HS 152 ± 65 min, EC 170 ± 70 min; $P=0.027$). First, the significantly lower blood loss in the HS group can be attributed to the reduced operating time. But it seems more likely that the decrease in average operating time with the HS was due to better hemostasis during surgery. On the other hand it seems somehow illogical to attribute a nearly 50% reduction in blood loss to an average of 20 min operation time reduction, when the average operating time was more than 3 h.

Although significantly fewer patients predonated autologous blood in the HS group, the number of retransfused patients was not significantly different

(Table 4). On the other hand there was a significant difference between the groups in the units of autologous blood donated and retransfused (Table 5), with exception of autologous RBC donated ($P=0.053$). With regard to this findings, two possible conclusions can be drawn. A possible insufficient calculation preoperatively for the EC group or a proper calculation for the HS group, which makes more sense, because of reduced blood loss with expected small divergences in blood loss for similar operations as shown by the figures for estimated total blood loss (HS 1106 ± 985 ml, EC 2176 ± 1764 ml). This reflects one of the unsolved problems in managing the blood requirements of orthopedic patients: the precise prediction of transfusion requirements. Nevertheless, the costs would not have changed very much if the number of patients predonating autologous blood in the EC group had been lower to maintain the retransfusion rate the same as in the HS group, which was 87% for FFP (26 retransfused patients of 30) and 82% for RBC (9 retransfused patients of 11). If 39 patients in the EC group had predonated FFP instead 41, and 20 patients RBC instead of 21, the retransfusion rate would be the same in both groups. But it should also be taken into consideration that the exposure to homologous blood products did not differ significantly between the groups (two vs five patients for RBC; one vs four patients for FFP), except for platelets (zero vs seven patients) with our predonation strategy.

A striking factor in both study groups was the huge amount of autologous FFP predonated. The Anesthesiology Department in our hospital, which is exclusively involved in cooperation with the orthopedic surgeons in the transfusion requirements of our patients, has systematically applied a comprehensive transfusion concept since 1984. With this concept most of the elective orthopedic operations done in our hospital are managed without homologous transfusion, except for tumor and septic surgery [16, 25, 26]. One of the main goals of this strategy is to collect rather more than less autologous plasma. The idea behind this strategy is that autologous FFP is the best and most physiological type of volume replacement. It is the most suitable material for reestablishing and maintaining postoperative normovolemia as it contains blood components such as antithrombin III, immunoglobulins and factor XIII, in contrast to artificial colloid solution [15, 25]. These claims are supported by different authors who have reported an increase in partial thromboplastin time and prothrombin time in the case of hydroxyethyl starch (HES), endothelial injury and capillary leak with different colloids, with possible leak of colloid solution into the interstitium with exertion of an osmotic gradient, pulling additional water into the interstitium [2, 24].

Because of reduced predonation of autologous blood products and less-frequent use of an IAT device,

the overall costs remained neutral, although the HS is an expensive device and the personnel costs for autologous blood predonation were not taken into consideration for the investment calculation. But emphasis must be given to the point that this device is only cost-neutral in cases with major anticipated blood loss. In fact the matched groups had an average loss of over 2 l, which of course is significant. If this device were to be used in operations with a much lower anticipated blood loss, then it would certainly not be cost-neutral.

One significant limitation of these and similar studies is the inability to establish strict control over the criteria used by the treating physicians in giving transfusions or even a complete absence of these data [3, 6, 29]. This issue is of special interest because Nuttal et al. [18] stated that the amount of retransfusion is statistically significantly related to the amount of autologous RBC available. In our study, the indications for transfusion of different blood products, with the exception of the IAT device use, were considered exclusively by the anesthesiologist.

The general criteria for transfusion of blood products used by our department have already been published and served as decision criteria in both groups [17]. Nevertheless, some relationship between the amount of autologous units available and the amount retransfused cannot be ruled out with certainty. The same is true for the amount of preoperative and postoperative hemoglobin, which was not analyzed in this study, and indeed is also a limitation of the present study.

In conclusion, the use of the HS in posterior spinal instrumentation resulted in a significant decrease in blood loss compared to EC. Therefore the amount of autologous blood predonation and the frequency of IAT device use was lower in the HS group, without an increase of homologous blood exposure, than in the EC group. Although the HS is an expensive device, cost neutrality was maintained due to the lower costs of different blood products. But emphasis must be given to the point that this device is only cost-neutral in cases with major anticipated blood loss.

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