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**Ultrasonically activated shears can
reduce estimated blood loss in open
distal gastrectomy for gastric cancer
: A randomized controlled study**

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위암 환자의 개복
위아전절제술에서의 초음파절삭기
사용으로 인한 실혈량 감소
: 전향적 무작위 임상시험

2014년 2월

서울대학교 대학원

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오 승 영

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**Ultrasonically activated shears can
reduce estimated blood loss in open
distal gastrectomy for gastric cancer
: A randomized controlled study**

by

Seung-Young Oh

A thesis submitted to the Department of Surgery
in partial fulfillment of the requirement of the
Degree of Master of Science in Medicine (Surgery)
at Seoul National University College of Medicine

December 2013

Approved by thesis committee:

Professor Young Tae Kim Chairman

Professor Han-Kwang Yang Vice Chairman

Professor Seung-Yong Jeong

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Abstract

Introduction: Although UAS have been used increasingly in open gastric surgery, only a limited number of randomized controlled studies have evaluated its safety and efficacy for this procedure. In addition, these studies used only a small number of patients or did not control for the type of anastomosis or surgery.

Methods: From October 2011 to November 2012, 56 gastric cancer patients eligible for open distal gastrectomy were randomized into a UAS dissection group (USD group) or a monopolar dissection group (MPD group; clinical trial registration number: NCT01971775). The primary endpoints were the estimated blood loss during surgery and amount of drainage through the 5th postoperative day. Secondary endpoints were operation time, hospital stay, serum laboratory results, inflammatory cytokine levels in the serum and peritoneal irrigation saline, cytology, and postoperative morbidity.

Results: The demographics and pathologic parameters were similar in both groups. The estimated blood loss was lower in the USD group than that in the MPD group (339.8 cc vs. 428.6 cc, $p = 0.021$). However, the amount of postoperative drainage was not significantly different between the two groups. In terms of the secondary endpoints, no statistical differences were observed between the two groups.

메모 [A5]: Formatting: The journal guidelines require this subheading in the abstract, and it should provide in a brief paragraph the scientific context of the study. A paragraph for this section has been written based on information in the main manuscript. Please check its appropriateness and revise as needed.

메모 [A6]: Formatting: The clinical trial registration number has been added to the abstract in accordance with the journal guidelines.

Conclusions: UAS can reduce blood loss and can be an alternative device for conventional monopolar electrocautery in open distal gastrectomy for gastric cancer.

Keywords: Ultrasonically activated shears (UAS), distal gastrectomy, gastric cancer

Student Number: 2012-21698

메모 [A7]: Formatting: The keywords have been deleted as a suggestion since the journal guidelines do not ask authors to provide them.

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Introduction

Ultrasonically activated shears (UAS) have been used in laparoscopic surgery since their introduction in the late 1900s(1-3) and have been applied recently to open surgery. UAS denature protein through ultrasonic energy, resulting in a sticky coagulum that can coat the vessel wall,(4, 5) and have been shown to occlude small- to medium-sized arteries as well as lymphatic vessels securely.(4-7) Previous reports dealing with various types of surgery have shown UAS to possess a number of advantages, including minimal thermal injury, reduced smoke, decreased operation time, and decreased intraoperative blood loss compared to conventional techniques.(1, 3, 8, 9)

Considering those various advantages of UAS, we could assume that using UAS would be able to reduce surgical stress. It has been reported that the reduced surgical stress resulted in the less inflammatory response which could affect positive effects on the perioperative morbidity and mortality.(10-12) These results were demonstrated by measuring the change in the level of representative inflammatory markers including C-reactive protein (CRP), interleukin 1 β (IL-1 β), interleukin 6 (IL-6), interleukin 10 (IL-10) and tumor necrosis factor- α (TNF- α).

Radical gastrectomy is the only curative treatment for gastric cancer,(13) and

메모 [A8]: A comparison is implied in this sentence, but the nature of the comparison is unclear. Please modify this phrase if needed to reflect more accurately the nature of the comparison.

open radical gastrectomy with D2 lymph node dissection has been until recently the gold standard in the treatment of advanced gastric cancer (AGC). As with other types of surgery, UAS have been increasingly used in open gastric cancer surgery; however, a high level of evidence for the use of UAS in this procedure has been provided by only a few randomized controlled studies. In one of these previous studies, Tsimoyiannis et al reported the efficacy of UAS in gastric cancer surgery; however, the number of patients was small, and the surgical procedures were not controlled.(14) Meanwhile, Choi et al used a greater number of patients, but did not control for the type of anastomosis.(15)

The study aim was to evaluate the efficacy of UAS through a comparison with conventional monopolar electrocautery in open distal gastrectomy for gastric cancer.

메모 [A9]: It appears that both references 11 and 12 should be provided at the end of this first highlighted sentence.

메모 [A10]: This section was revised for improving the reasoning. That is, you mention one of the previous randomized controlled studies but not the other study. The mention of only one study may puzzle readers, since several are noted as published. Moreover, it makes the paragraph incomplete, since it appears the overall purpose is to address the inadequacies of the previous studies to form the basis of your own. Hence, expanding this section to include the Choi et al. study has been suggested. However, you may need to modify the statement to more accurately reflect its limitations. Moreover, it appears that the study of Wilhelm et al. should be integrated into this brief description of previous studies.

Materials and Methods

Patients

This was a prospective randomized controlled study performed at Seoul National University Hospital (SNUH) from October 2011 to November 2012. A total 56 patients who underwent open radical subtotal gastrectomy with Billroth I anastomosis for gastric cancer were enrolled and randomly assigned to the monopolar dissection group (MPD group) and ultrasonic dissection group (USD group). All the patients were diagnosed with gastric adenocarcinoma at clinical T stage 1 to 3. Because of the plan to perform cytology assays, we excluded patients with the possible diagnosis of clinical T stage 4. This study was approved by the institutional review board of SNUH, Seoul, Korea, and registered on ClinicalTrials.gov (clinical trial registration number: NCT01971775).

Sample Size

The primary endpoints were estimated blood loss (EBL) and abdominal drainage amount. The sample size was calculated using the software program PASS 2008 ver. 8.0.5 (NCSS, LLC, Kaysville, Utah, USA) based on the

results of a previous study reported by Tsimoyiannis et al in 2002(14) and Bonferroni's adjustment. In the study of Tsimoyianis et al, the USD group and the MPD group showed significantly differences in the EBL (318 ± 163 ml vs. 580 ± 198 ml, $p<0.001$) and the abdominal drainage amount (480 ± 242 ml vs. 985 ± 602 ml, $p<0.002$). Using two-tailed t-test with $\alpha=0.05$ and $\beta=0.2$, the minimum numbers of patients for detecting differences between the two groups were 14 in the EBL (power=91.9%) and 23 in the abdominal drainage amount (power=90.8%). We picked the larger number, 23 patients in each group and based on a drop-out rate of 15%, total 28 patients were required in each group.

Study Protocol

Only the assigned device was used for omentectomy, lymph node dissection, and other routine procedures of distal gastrectomy. A Harmonic Scalpel (Ethicon Endo Surgery, Inc., USA) was used in the USD group, whereas conventional monopolar electrocautery was used in the MPD group. In both groups, we used clips or applied ties for the ligation of major vessels, including bilateral gastroepiploic and gastric vessels.

Irrigation was not performed during the surgery in order to allow an exact estimation of blood loss. For the cytokine and cytology assays, we applied

200 cc of normal saline for peritoneal irrigation just after laparotomy and then aspirated as much of the irrigated saline as possible. Of the saline aspirated after peritoneal irrigation, 5 cc was sent for the cytokine assays, and the remaining saline was sent for centrifugation (Cytospin, Shandon Southern Instruments, Pittsburgh, PA, USA) in preparation for the cytology assays. Further, the specimens were washed with 200 cc of normal saline just after the resection. Before wound closure, we repeated the same procedure of peritoneal irrigation using 200 cc of normal saline.

Blood loss was measured by the sum of the suctioned blood and the differences between the non-used and used gauzes. Because absorbed blood can dry on gauze, the used gauzes were weighted immediately after use.

During the postoperative period, the amount of abdominal drainage was checked every 24 hours from the end of the operation to the 5th postoperative day. For the serum laboratory tests and cytokine assays, we collected an additional ethylenediaminetetraacetic acid bottle of blood during routine blood collection, which was performed after gastrectomy and at postoperative days (PODs) 2, 5, and 7 in accordance with the standard procedure at SNUH.

For the maintenance of accurate time intervals in serum laboratory tests and cytokine assays, we arranged the surgery of the enrolled patients to the 1st case of the day, sampled blood at the same time in the morning of each day and sampled abdominal drainage of the POD 1 exactly 24 hours after the

메모 [A11]: A number of company locations are possible for this product. One possibility has been provided. Please substitute with the correct location if applicable.

메모 [A12]: Please check that this revision has not changed your intended meaning.

If I have altered your meaning, you might also consider this revision: "For the serum laboratory tests and cytokine assays, we collected an additional ethylenediaminetetraacetic acid bottle of blood after gastrectomy and at postoperative days (PODs) 2, 5, and 7 during routine blood collection performed in accordance with the standard procedure at SNUH."

메모 [A13]: This final statement regarding the assay has been removed as a suggestion because this type of justification is not generally stated in academic articles.

surgery.

Statistical Analysis

Comparisons between the two study groups were tested with the Student's *t*-test and χ^2 test. The Mann-Whitney U test and Fisher's exact test were used for continuous and categorical variables, respectively. The differences in the change of the level of cytokines between the two groups were analyzed using repeated measured ANOVA method. A *p*-value of <0.05 was considered statistically significant.

메모 [A14]: Authors typically note the p value at which significance is considered to occur. Please check this suggested statement.

Results

Of the 56 randomized patients, 7 patients (4 patients from the MSD group; 3 patients from the USD group) were excluded from the study because the gastric cancer was at a more advanced stage than at the preoperative examination (2 patients), a change in the type of surgery needed for obtaining a sufficient resection margin (3), an unexpected combined resection (1) and a missed asymptomatic abnormal preoperative laboratory result (1). The drop rate was 12.5% which was lower than we had considered during designing of this study. Hence, a total of 49 patients, 24 patients in the MSD group and 25 patients in the USD group, were finally analyzed (Figure 1).

No significant differences were observed between the two groups in terms of age, sex, and the body mass index. Moreover, the final pathologic results, including the T stage, the N stage, and the overall stage were not statistically different between the two groups (Table 1).

Among the operative results, the EBL was significantly reduced in the USD group compared to that in the MPD group (339.8 cc vs. 428.6 cc, $p = 0.021$). Moreover, the operation time was also decreased in the USD group relative to that in the MPO group, although the difference was not statistically different

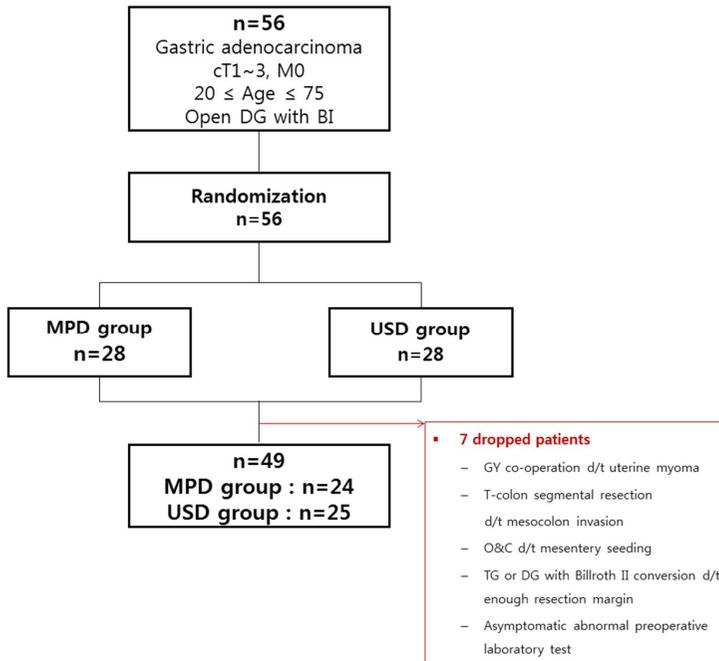
between the two groups. In addition, the hospital stay, amount of abdominal drainage, and complication rates showed no differences between the two groups (Table 2). A detailed analysis of each type of observed complication also showed no significant differences between the two groups (Table 3). In the MPD group, 3 cases of intra-abdominal bleeding requiring transfusion and 1 case of gastroduodenostomy leakage were detected. In the USD group, no cases of intra-abdominal bleeding occurred; however, 1 case of pancreatic fistula and 1 case of partial splenic infarction were observed.

In terms of the serum laboratory tests, no significant differences were found in hemoglobin, C-reactive protein, and amylase between the two groups at any of the evaluated time points (Table 4). Additionally, the cytokine assays of the serum and peritoneal irrigation saline showed no significant differences between the two groups (Figures 2 and 3).

In both the MPD and USD groups, no cases were positive for cancer cells in the preoperative and specimen cytology results. Of the total patients, only one patient in the USD group was cancer cell positive based on the postoperative cytology assay. However, no statistical differences were found between the two groups, indicating the two devices have a similar ability to seal lymphatic vessels during surgery (Table 5).

메모 [A15]: This information was moved from the end of the results section because a large number of one-sentence paragraphs is typically avoided in academic writing.

Figure 1 Flow diagram of the study population



메모 [A16]: Formatting: Please submit the figures at a minimum resolution of 1200 dpi and as files separate from the manuscript. Once the figures have been removed from the manuscript, the figure legends should be consolidated on a page after the references.

Please submit Figure 1 as a TIFF, EPS, MS Office (DOC, PPT, XLS), or high-resolution PDF file. Also, please insert a space on either side of the equal sign. Please use black coloration instead of red for the lower box and the font.

DG, distal gastrectomy; GY, gynecology; O&C, open and closed; TG, total gastrectomy.

Table 1 Demographics

	MPD group (n = 24)	USD group (n = 25)	<i>p-value</i>
Age (yr)	58.5 ± 8.2	54.7 ± 0.1	0.159 ¹⁾
Sex (M:F)	17:7	18:7	1.000 ²⁾
BMI (kg/m ²)	24.3 ± 2.1	23.4 ± 2.9	0.208 ¹⁾
T stage			0.171 ³⁾
T1	10 (41.7%)	5 (20.0%)	
T2	8 (33.3%)	6 (24.0%)	
T3	5 (20.8%)	11 (44.0%)	
T4a	1 (4.2%)	3 (12.0%)	
			0.464 ³⁾
N0	13 (54.2%)	11 (44.0%)	
N1	6 (25.0%)	5 (20.0%)	
N2	1 (4.2%)	5 (20.0%)	
N3	4 (16.7%%)	4 (16.0%)	
TNM stage (I:II:III)	13:8:3	7:11:7	0.157 ³⁾
BMI, body mass index			

메모 [A17]: The footnotes has renumbered because no footnote for the Student t-test was placed in the table. Please check.

1) Student's *t*-test 2) χ^2 test 3) Fisher's exact test

Table 2 Operative results

	MPD group (n = 24)	USD group (n = 25)	<i>p-value</i>
Operation time (min)	177.54 ± 29.7	167.7 ± 28.6	0.244 ¹⁾
Estimated blood loss (cc)	428.6 ± 165.8	339.8 ± 201.2	0.021 ²⁾
Abdominal drainage (cc)	702.9 ± 321.3	906.5 ± 496.6	0.285 ²⁾
Hospital stay (days)	8.5 ± 3.3	10.3 ± 10.0	0.954 ²⁾
Complication, any	7 (30.4%)	7 (28.0%)	0.853 ³⁾
Local	5 (20.8%)	6 (24.0%)	0.791 ³⁾
Systemic	2 (8.3%)	1 (4.0%)	0.609 ⁴⁾

1) Student's *t*-test 2) Mann-Whitney test 3) χ^2 test 4) Fisher's exact test

Table 3 Operative results

	MPD group (n = 24)	USD group (n = 25)	<i>p-value</i> ¹⁾
Wounds	1 (4.2%)	3 (12.5%)	0.609
Fluid collection	0 (0.0%)	1 (4.0%)	1.000
Intra-abdominal bleeding	3 (12.5%)	0 (0.0%)	0.110
Intestinal stenosis	0 (0.0%)	1 (4.0%)	1.000
Motility disorder (Ileus)	0 (0.0%)	1 (4.0%)	1.000
Anastomosis leakage	1 (4.2%)	1 (4.0%)	1.000
Other leakage	0 (0.0%)	1 (4.0%)	1.000
Ischemia	0 (0.0%)	1 (4.0%)	1.000
Pulmonary complications	1 (4.2%)	1 (4.0%)	1.000
Urinary complications	1 (4.2%)	0 (0.0%)	0.490

1) Fisher's exact test

메모 [A18]: "Pulmonary" and "Urinary" are adjectives and therefore require a noun. "Complications" has been offered based on the context; however, please replace with a more appropriate, if needed.

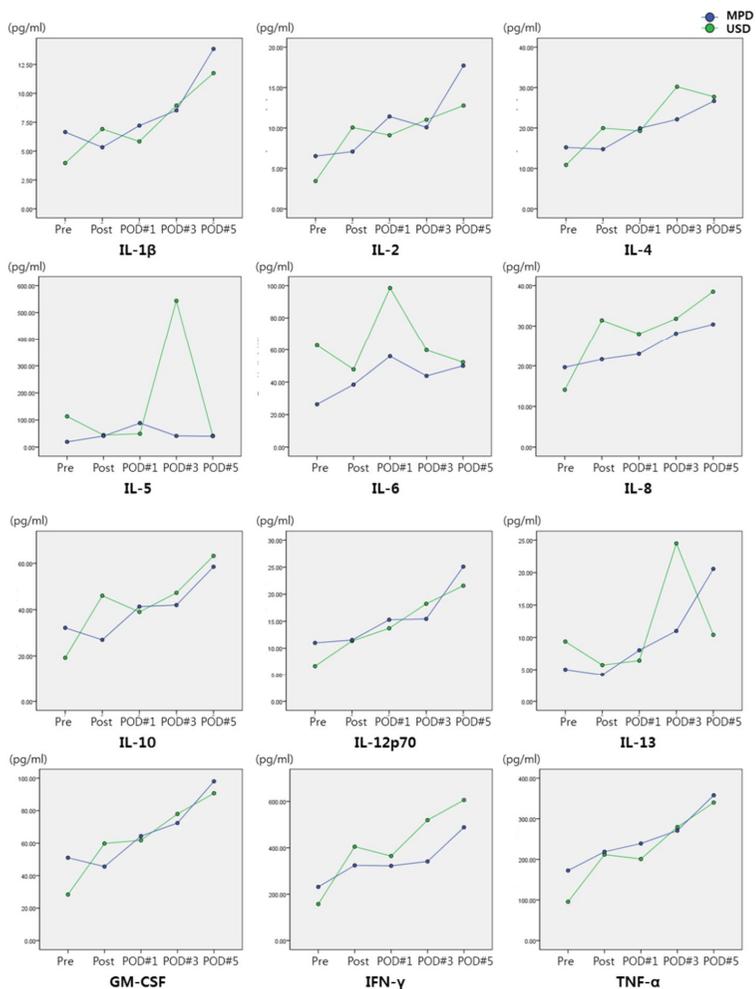
Table 4 Serum laboratory tests

	MPD group (n = 24)	USD group (n = 25)	<i>p</i> -value
Hb			
Preoperative	13.4 ± 1.4	13.5 ± 1.9	0.826 ¹⁾
POD #2	11.7 ± 1.7	11.9 ± 1.2	0.550 ¹⁾
POD #5	11.7 ± 1.2	11.8 ± 1.4	0.715 ¹⁾
POD #7	12.1 ± 1.1	12.7 ± 2.7	0.238 ²⁾
CRP			
Preoperative	0.2 ± 0.4	0.1 ± 0.1	0.344 ²⁾
POD #2	12.0 ± 6.5	12.3 ± 4.8	0.535 ²⁾
POD #5	5.2 ± 3.2	5.9 ± 4.3	0.909 ²⁾
POD #7	3.4 ± 2.8	4.4 ± 5.3	0.886 ²⁾
Amylase			
Preoperative	61.3 ± 25.1	61.1 ± 15.8	0.967 ¹⁾
POD #2	97.4 ± 147.5	101.6 ± 127.4	0.862 ²⁾
POD #5	81.4 ± 47.3	117.0 ± 123.9	0.555 ²⁾
POD #7	72.0 ± 43.3	97.7 ± 79.6	0.250 ²⁾

Hb, hemoglobin; CRP, C-reactive protein; POD, postoperative day.

1) Student's *t*-test 2) Mann-Whitney test

Figure 2 Results of the serum cytokine assays



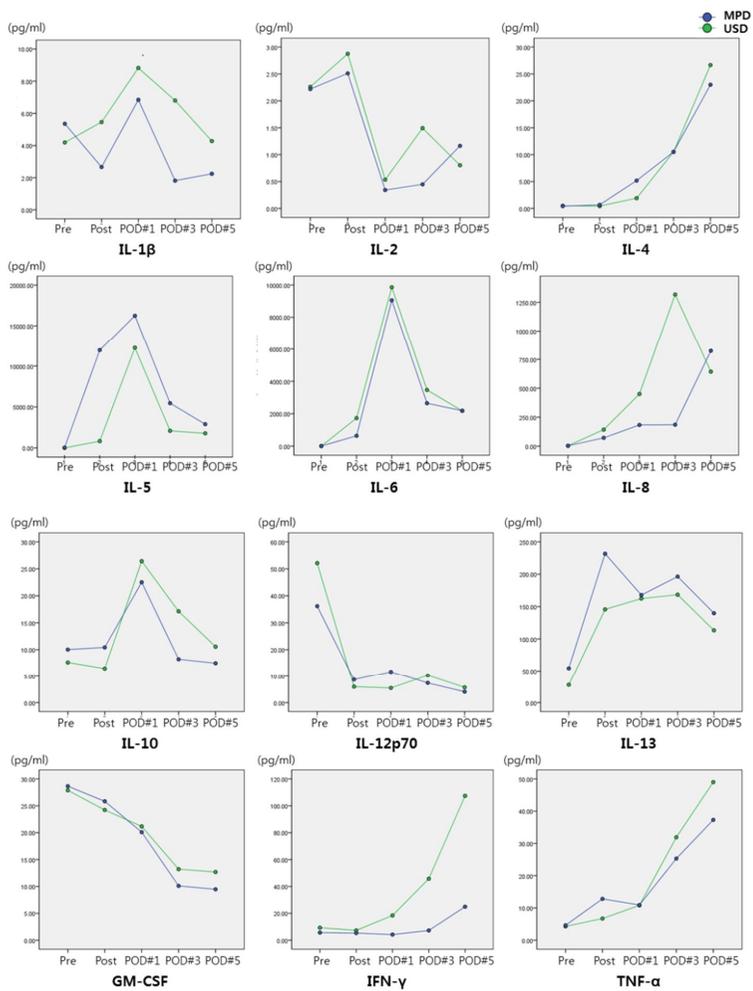
메모 [A19]: Formatting: Please submit Figures 2 and as a TIFF, EPS, MS Office (DOC, PPT, XLS).

Graphs are typically in black-and-white and not in color because of publication costs and because the color usually does not provide additional information. Hence, you should consider making the graphs black and white.

What are the measurements of unit for the various cytokines? If it is the same for all of them, it can be noted in the figure legend.

IL, interleukin; GM-CSF, granulocyte-macrophage stimulating factor; IFN, interferon; TNF, tumor necrosis factor

Figure 3 Results of the peritoneal irrigation saline cytokine assays



IL, interleukin; GM-CSF, granulocyte-macrophage stimulating factor; IFN, interferon; TNF, tumor necrosis factor

Table 5 Cytology assays

	MPD group (n = 24)	USD group (n = 25)	<i>p-value</i> ¹⁾
Preoperative cytology			1.000
Negative	23 (95.8%)	23 (92.0%)	
Atypical cell	1 (4.2%)	2 (8.0%)	
Positive	0 (0.0%)	0 (0.0%)	
Others	0 (0.0%)	0 (0.0%)	
Postoperative cytology			1.000
Negative	22 (91.7%)	23 (92.0%)	
Atypical cell	1 (4.2%)	1 (4.0%)	
Positive	0 (0.0%)	1 (4.0%)	
Others	1 (4.2%)	0 (0.0%)	
Specimen cytology			0.235
Negative	22 (91.7%)	25 (100.0%)	
Atypical cell	0 (0.0%)	0 (0.0%)	
Positive	0 (0.0%)	0 (0.0%)	
Others	2 (8.4%)	0 (0.0%)	

1) Fisher's exact test

Discussion

Unlike previous randomized controlled studies addressing the efficacy and safety of UAS in open gastric cancer surgery,(14, 15) the present study limited inclusion based on the type of anastomosis and surgery. Our findings indicate UAS can reduce blood loss and can be an alternative device for conventional monopolar electrocautery in open distal gastrectomy for gastric cancer.

The primary endpoint of EBL was significantly different between the two study groups. However, the values of both groups were much greater compared to those of previous studies on open distal gastrectomy for advanced gastric cancer.(15, 16) The difference between these studies and the present one could have been the result of the study protocols, including the peritoneal irrigation performed for the cytology assay in our study. Of note, the amount of irrigated saline collected after 200 cc of normal saline irrigation was less than 150 cc in most cases. Given that the procedure was performed twice, approximately 100 cc of irrigated saline could have contributed to the EBL as a result of the gauze weight measurements.

In the present study, no differences in the operation time were observed between the MPD and UAS groups. Two randomized controlled trials that

메모 [A20]: Authors typically use the first paragraph to note the study highlights. Hence, this paragraph has been expanded slightly to inform readers of the importance of the study. You may wish to add additional statements.

compared UAS to conventional monopolar electrocautery in gastrectomy for gastric cancer also reported that the operation time was not statistically different.(14, 17) Hence, our results are consistent with these previous findings. However, the recent randomized controlled study of Choi et al reported a significantly shorter operation time in the USD group.(15) One possible explanation is that the first two studies and the current one used only the assigned device in each group, whereas the third study used monopolar electrocautery in both groups. Because either device can provide greater convenience than the other at certain points during a gastrectomy, the operation time can be shortened if the procedure is performed with both devices. A consideration of the findings for the EBL and operation time suggests that the application of more ties in the MPD group for achieving meticulous hemostasis could reduce blood loss but increase the operation time.

Based on previous studies reporting differing extents of tissue damage based on the type of energy-based device,(18-20) we hypothesized that the inflammatory reaction resulting from thermal tissue damage would be different between the two groups. However, no differences in the cytokines in the serum and peritoneal irrigation saline were found between the two groups. The difference in the peak temperature between the active blades of the two devices could be an explanation for this lack of a difference.

In the present study, the results of the cytology assays demonstrated that the

메모 [A21]: You might note I have been reducing the number of times "statistical" is mentioned in the Discussion. In academic writing, "significant" and "significantly" are used almost exclusively to denote statistical significance. Hence, the use of "statistical" is not needed each time a statistical difference is being discussed. Based on convention, the reader will understand you are referring to statistical significance.

메모 [A22]: Please check that I have correctly conveyed your intended meaning. You may wish to use a more precise phrase than "at certain points."

USD had an acceptable level of ability to seal lymphatic vessels during the lymph node dissection. Free cancer cells can be released from lymphovascular pedicles during gastric cancer surgery(21) and can result in positive cytological findings, which is a risk factor of recurrence.(22) Because lymph node dissection is a mandatory procedure accompanying radical gastrectomy for gastric cancer, the sealing of lymphatic vessels as well as blood vessels is important. Our findings provide further evidence that USDs possess a sufficient ability to seal lymphatic vessels, as shown previously by Abe et al.(7) Despite the various evidence for the superiority or non-inferiority of UAS compared to monopolar electrocautery, there has been controversy regarding the generalization of UAS for different procedures in relation to coverage and therefore cost-effectiveness. The Korean health insurance system covers the fee for the use of UAS only in laparoscopic surgeries, not in open surgeries, resulting in patients paying an extra fee. For resolving this issue, further study regarding the relation between the operator's comfort and surgical outcomes should be established.

메모 [A23]: I was uncertain how this statement related to the previous statements. Are you indirectly stating that lack of familiarity with the device is impeding the willingness to adopt the device and causing worse outcomes than necessary when it is used? If so, are you stating this is resulting in an unwillingness by the Korean health insurance company to cover it? Please provided any needed clarifications, and I would be happy to revise this text further.

Conclusions

Based on the study findings, UAS is a safe and effective device with sufficient ability for sealing lymphatic vessels as well as small- to medium-sized arteries in open distal gastrectomy for gastric cancer. Moreover, UAS can decrease blood loss and may reduce operation time if used with monopolar electrocautery.

Acknowledgments

메모 [A24]: If applicable, you can also acknowledge those who contributed to the study but did not qualify for authorship (e.g., those who provided technical support).

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국문 초록

서론: 최근 복강경 수술에서 뿐만 아니라 개복 수술에서도 초음파절삭기의 사용이 증가하고 있다. 이 연구에서는 위암 환자의 개복 위아전절제술에서 초음파절삭기와 전기소작기를 비교하는 전향적 무작위 임상실험을 통해 초음파절삭기의 효용성을 검증해보고자 한다.

방법: 2011년 10월부터 2012년 11월까지 서울대병원에서 위암으로 인해 개복 위아전절제술을 시행해야하는 56명의 환자들을 전기소작기 그룹과 초음파절삭기 그룹에 무작위 배정한 후 실혈량, 수술 후 5일째까지의 복부 배액량, 수술 시간, 입원 기간, 합병증, 혈액 및 복부 세척액에서의 사이토카인 분석, 세포검사 등을 비교 분석하였다.

결과: 전기소작기 그룹과 초음파절삭기 그룹 간의 임상병리학적 양상은 유사하였다. 수술 중 실혈량은 초음파절삭기 그룹에서 통계적으로 유의하게 적은 것으로 나타났지만, 다른 변수들에서는 두 그룹 사이에 통계적으로 유의한 차이점은 나타나지 않았다.

결론: 위암 환자의 개복 위아전절제술 시 초음파 절삭기의 사용은

안전하고 전기소작기와 유사한 효과를 기대할 수 있으며, 특히 수술 중 실혈량을 줄여줄 수 있다.

주요어: 초음파절삭기, 위아전절제술, 위암

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