

The Advantages of the Harmonic Scalpel® for the Harvesting of Radial Arteries for Coronary Artery Bypass

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Creighton B. Wright, MD,¹ Hendrick B. Barner, MD,² Aijun Gao, PhD,³ Renee Obial, MSRN,¹
Bruce Bandy,¹ Loretta Perry, RN,² John Ronan, BSN,² Colleen R. Kelly, MS³

¹Jewish Hospital, Cincinnati, OH

²Washington University School of Medicine, St. Louis, MO

³Ethicon Endo-Surgery, Inc., Cincinnati, OH

ABSTRACT

Background: Improvements in replacement vessel harvesting techniques and antispasmodic agents since the 1970s have led to a resurgence of interest in the radial artery (RA) as a conduit for coronary revascularization.

Methods: This randomized study compared the Ultra Cision Harmonic Scalpel® (HS) (Ethicon Endo-Surgery, Inc., Cincinnati, OH) and the cold steel scalpel (CSS) for harvesting radial arteries to be used in coronary artery bypass grafting (CABG) procedures. Men and non-pregnant women, aged 21 to 79 years, with myocardial ischemia or coronary stenosis who were scheduled to undergo coronary bypass were enrolled in the study.

Results: Harvesting of the radial artery by the Harmonic Scalpel required a significantly lower number of clips to control bleeding. There was no significant difference between the times required to harvest the artery with either device. There were no complications, malfunctions, or serious adverse events associated with the use of either device.

Conclusions: The Harmonic Scalpel provides excellent control of bleeding compared to the cold steel scalpel, and its use permits bleeding to be controlled without the need for potentially damaging electrocautery. No clinically significant adverse events were associated with the use of the Harmonic Scalpel.

INTRODUCTION

Carpentier [Carpentier 1973] was the first surgeon to propose using the radial artery (RA) as a conduit for revascularization during coronary artery bypass grafting (CABG) procedures. However, because of RA spasm, which induced a 35% incidence of vessel occlusion, he later abandoned this procedure [Carpentier 1975]. The vasospasm was thought to be a consequence of the trauma of the harvesting procedure and/or thermal injury resulting from electrocautery [Acar 1992, Dietl 1995]. Graft occlusion resulting from subintimal

hyperplasia was another factor that militated against the use of the RA [Curtis 1975].

Since these early attempts, the use of new pharmacologic antispasmodic agents (e.g., Ca++ channel blockers) and improved methods for harvesting replacement vessels have resulted in enhanced arterial patency and a resurgence in the use of RA grafts for CABG [Hayes 1998]. Comparative studies showed that use of the radial artery improved the results of CABG surgery [Acar 1991] perhaps because the radial artery is of good size and easier to anastomose sequentially than several of the other arterial conduits. The use of the radial artery is a significant aspect of the "all arterial conduit" approach that is currently favored and which is associated with improved long-term results.

The Ultra Cision Harmonic Scalpel® (HS) (Ethicon Endo-Surgery, Inc., Cincinnati, OH) is used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels. The quality of radial arteries for CABG procedures has improved as a result of using the HS rather than blunt and sharp dissection procedures. Ultrasonic dissection of the RA with the HS has resulted in less spasm and a marked decrease in the number of clips required to control bleeding [Ronan 2000]. Because this technique obviates the use of electrocautery, the possibility of thermal damage is reduced. Furthermore, while the surgeon is able to identify nerve structures, the use of the HS minimizes trauma to these structures, which could result in vessel spasm.

This study was designed to compare the HS and the cold steel scalpel (CSS) for the harvesting of radial arteries for subsequent CABG procedures. Relevant information was collected on pre- and post-harvest artery quality, harvesting time, the number of clips used, neurological and morbidity parameters (such as range of arm movement), and post-bypass patency (as assessed by angiography in the three-month postoperative period).

MATERIALS AND METHODS

This study was a randomized comparison of the HS and the CSS for the harvesting of the RA, performed at two study sites. There were five visits: screening (to assess study eligibility); the surgical procedure; and three postoperative

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Address correspondence and reprint requests to: Creighton B. Wright, MD, Cardiovascular Surgeons, 2123 Auburn Ave., Suite 401, Cincinnati, OH 45219, Phone: (513) 421-3494, Fax (513) 345-2606, Email: cbw@one.net

Table 1. Demographic characteristics

Characteristic		Harmonic Scalpel® (N = 26)	Cold Steel Scalpel (N = 25)
Age (years) (mean ± SD)		59 ± 10	63 ± 9
Sex:	Male	23 (88%)	20 (80%)
	Female	3 (12%)	5 (20%)
Race:	Caucasian	24 (92%)	20 (80%)
	Black	2 (8%)	4 (16%)
	Other	0	1 (4%)
Tobacco Use			
Prior Use:	Yes/No	23 (88%)/3 (12%)	18 (72%)/7 (28%)
Current use:	Yes/No	9 (35%)/17 (65%)	5 (20%)/20 (80%)

examinations (one day, one-to-two weeks, and three months after the surgical procedure).

Patient Population

Men and non-pregnant women between the ages of 21 and 79 years were enrolled in the study. The subjects had been diagnosed with myocardial ischemia or coronary stenosis and were scheduled to undergo a CABG procedure, using the RA as a graft. Adequate collateral blood flow in the hand and normal skin sensitivity in the dorsal lateral dermatome were required for study eligibility. Each patient signed an informed consent before participating in the study and was available to attend the required follow-up visits. Patients with a history of Raynaud's syndrome and/or vasculitis, ipsilateral cervical disc disease, and/or carpal tunnel syndrome, or who required a concomitant valve repair were not eligible. Likewise omitted were patients who were immunocompromised or had any radial artery, radial nerve, compartment syndrome, or psychiatric condition or disorder that would have prevented harvesting of the radial artery or valid postoperative evaluation.

Patients were assigned to a device group by randomization code and did not know which device was used for their surgery. Twenty-six patients underwent the harvesting procedure using the HS and 25 using the CSS. The two device groups were similar in demographic characteristics, as shown in Table 1 (●).

Harmonic Scalpel Device

The Harmonic Scalpel is an ultrasonic instrument for cutting and coagulating tissue that operates at a frequency of 55.5kHz. It consists of a generator, hand piece, and disposable blade. The 10cm or 14cm disposable hook blade accomplishes tissue dissection coagulation by delivering heat generated by ultrasonic vibration of tissue. Bleeding is controlled by coaptive coagulation, in which vessels are tamponaded and sealed by a protein coagulum. This form of mechanical energy produces less heat and less smoke during tissue dissection than does regular electrocautery.

Surgical Procedure

The collateral circulation to the hand was assessed by the surgeon using the modified Allen test. Both the radial and

ulnar arteries were occluded and the patient asked to tightly close his/her hand ("make a fist") for 30 seconds. The patient then relaxed the tight fist, the ulnar artery was released (with the RA still occluded) and the time for complete capillary refilling of the palmar surface of the hand was measured (in seconds), with particular attention to the thumb. Refilling within 12 seconds was acceptable for harvesting. The harvesting was usually from the non-dominant arm unless the modified Allen test was positive, in which case the dominant arm (if negative) was used.

The supinated arm was extended at 90° from the body, prepared, and draped. A curved incision was made over the RA, extending from the antecubital fossa to the proximal wrist crease, with the middle third swinging towards the ulna, to facilitate mobilization of the lateral antebrachial cutaneous nerve, in the lateral flap of skin and subcutaneous tissue. The incision was carried to the fascia, which could be opened proximally with either the HS or scissors and distally with the scissors, because of the proximity of the RA, and the course of the artery identified. The mid-pedicle (artery, veins, and areolar tissue) was encircled with a silastic loop and dissection initiated with gentle traction on the loop. The HS with the hook blade was used to dissect the artery and its branches; clips were used only if a branch bled on its proximal side. With the CSS, the branches were exposed by blunt and sharp dissection (scissors) and divided between small clips. After the desired length of the RA had been mobilized, it was suture ligated (4/0 suture) at each end, sharply divided, and placed in heparinized blood containing papaverine (2 mg/ml) at room temperature. Hemostasis was obtained in the HS group using the HS alone, and in the CSS group by electrocautery. The arm was then closed in layers with absorbable suture, a bulky dressing applied, and the arm returned to the patient's side.

Efficacy Parameters

The efficacy parameters were as follows: (1) Radial artery harvest time—the time from radial artery skin incision to the final arterectomy; (2) Number of clips used during the procedure—a count of the clips used to control bleeding; (3) The quality of the RA and its pedicle for anastomosis—assessed after harvesting and after anastomosis, prior to closing of the chest. These were visual assessments to determine the adequacy of the arteries for anastomoses and to confirm the absence of spasm and hematoma; and (4) Success of the coronary bypass graft anastomosis—assessed intra-operatively and at the three-month postoperative evaluation, and confirmed by lack of clinical evidence of myocardial ischemia necessitating angiographic evaluation. In those patients requiring coronary angiography during the three-month postoperative period, graft patency was directly determined.

Safety Parameters

Safety was monitored throughout the study. Adverse events were recorded as well as the following assessments related to the safety of the surgical devices: (1) Range of arm movement—measured in the arm from which the RA was harvested and assessing carpal joint extension, carpal joint flexion, elbow extension, and elbow flexion; (2) Superficial

Table 2. Primary efficacy parameters: comparison of surgical devices

Efficacy parameter	Harmonic Scalpel® (N = 26)	Cold Steel Scalpel (N =25)	P-value*
Time of harvesting (min.) [median (min.-max.)]	39 (25-96)	36 (28-56)	0.26
Number of clips used [median (min.-max.)]	0 (0-28)	69 (25-102)	<0.001
Number of patients requiring angiography within three-month postoperative period	1 (4%)	2 (8%)	Not done

*Wilcoxon Rank-Sum test

radial nerve damage—evaluated by assessment of dyskinesia, dystaxia, and dysesthesia of the thumb/forefinger/back of hand; (3) Lack of hand collateral flow in the operative arm; (4) Morbidity—evaluated by assessment of, but not limited to, infection and ischemia; (5) Wound morbidity—evaluated by assessment of, but not limited to, cellulitis, hematoma, separation, and draining; and (6) Mortality.

Statistical Methods of Assessment

Changes in the quality of the radial artery were assessed from pre-harvest to post-harvest and to post-bypass by creating 3x3 frequency shift tables. The symmetry (or agreement) of the overall radial artery quality between each pair of time points (pre- to post-harvest, and pre-harvest to post-bypass) was tested by Bowker's test and by a simple Kappa coefficient. Satisfactory harvesting of the radial artery was also assessed by determination of the intra-operative incidence of spasm, hematoma, and debris. Radial artery anastomosis assessments for primary site and distal site were calculated as percents observed per group.

The median harvest times and median number of clips used were compared by the Wilcoxon Rank-Sum test.

RESULTS

Efficacy

All 51 patients completed the surgery, but two HS patients and four CSS patients did not complete the follow-up requirements of the protocol. In the CSS group, one patient died due to gastrointestinal hemorrhaging (not related to the use or malfunction of the device) and three others failed to return for follow-up; in the HS group one patient was lost to follow-up and another withdrew consent.

The median time to harvest the RA and the median number of clips used during the procedure are summarized in Table 2 (●). There was no significant difference ($p = 0.26$) between the two devices in the median time required to harvest the RA.

The median number of clips required to control bleeding when the procedure was performed with the HS was 0 (range of 0-28), which was significantly less ($p < 0.001$) than the median of 69 clips (range of 25-102) used when the procedure was performed with the CSS. The HS provided better control of bleeding, which was accomplished without the potential for thermal injury associated with the use of electrocautery.

Before the start of the harvesting procedure, all but one of the arteries in each device group were judged to be of good quality (no evidence of spasm and/or hematoma); the remain-

ing arteries were of fair quality. None of these quality assessments changed at post-harvesting and post-anastomosis evaluation, indicating that the HS had no adverse effects on the quality of the artery for transplantation.

The success of anastomoses was confirmed at the three-month follow-up visits (Table 2, ●); only three patients (one in the HS group and two in the CSS group) had required angiography within the three-month postoperative period. None of the patients had > 20% stenosis in the grafted vessels.

Safety

The harvesting procedure had little effect on the range of motion of the arm from which the artery was taken. One patient in the CSS group who had normal range of motion at screening subsequently had limited carpal joint extension at the three-month follow-up visit. Conversely, two patients in the HS group, both with limited carpal joint extension and flexion at screening, and two patients in the CSS group, one with limited carpal joint extension and one with limited elbow flexion at screening, all had normal motion at the three-month follow-up visit.

There was no evidence of lack of collateral blood flow in the hand, ischemia, or infection in the arm from which the RA was harvested. In addition, no wound morbidity, as indicated by the presence of cellulitis, hematoma, separation, or draining, was observed.

None of the adverse events that occurred during the study were considered to be related to the use or malfunction of either device. The adverse events that occurred were instead related to the underlying disease state of the study population, in particular their cardiovascular deficiencies. One patient in the CSS group died two days after his bypass procedure, when he required gastrointestinal surgery for a transmural necrosis of the colon and gastrointestinal bleeding. This patient refused blood transfusions because of his religious beliefs and subsequently died. His death was not related to the use of the surgical device.

DISCUSSION

Early attempts to use the radial artery as a source of conduits for CABG procedures were not successful due to spasm and denervation of the harvested arteries [Carpentier 1975]. These problems arose from the trauma of harvesting and/or from the thermal injury caused by the electrocautery that was used to contain bleeding. However, the use of new pharmacologic antispasmodic agents (e.g., Ca^{++} channel blockers) and improved methods for harvesting replacement vessels

have resulted in a resurgence of the use of RA grafts for CABG surgery [Hayes 1998].

The HS is a relatively new device that was first approved for use in 1989. It is intended for use in surgical procedures where cutting and coagulation of soft tissue is involved, and where minimal thermal injury is desired. One such procedure is the harvesting of the radial artery as a conduit for revascularization in patients who have been scheduled to undergo CABG. A recent study has suggested that the HS may be the device of choice for harvesting these vessels [Ronan 2000]. The present study confirms these earlier findings that the HS can be used successfully to harvest radial arteries for CABG procedures.

Compared to the CSS harvesting procedure, the number of clips that was required to control bleed was significantly reduced. Fourteen patients (54%) whose RAs were harvested by the HS did not require any clips, whereas all 25 patients whose RAs were harvested using the CSS required at least 25 or more clips. Complete harvesting time with the HS (39 min.) was comparable to CSS (36 min.) and the difference was not clinically or statistically significant.

Neither device caused injury to the harvested vessels, and the successful grafting with these vessels was evident from the low rate of angiography for suspected stenosis required at the three-month postoperative follow-up (HS: 4% (1/26 patients); CSS: 8% (2/25 patients)). No complications, malfunctions, or adverse events arose with the use of the HS for the surgical procedure.

CONCLUSION

This study shows that the HS offers much better control of bleeding than the CSS when it is used to harvest radial arteries in patients scheduled to undergo CABG, and that bleeding can be contained without the use of potentially damaging electrocautery. The HS did not cause any safety problems, and no postoperative damage to the arm from which the RA was harvested was observed. The results of this study support those of a previous study [Ronan 2000] which indicated that the HS is the device of choice for the harvesting of radial arteries for subsequent transplant procedures.

Disclosure

This study was sponsored by a grant from Ethicon Endo-Surgery, Inc. Aijun Gao, PhD and Colleen R. Kelly, MS are employed by Ethicon Endo-Surgery, Inc.

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REVIEW AND COMMENTARY

1. Editorial Board Member KE221 writes:

- a) Explain the following inconsistency in data: Table 2 describes the median number of clips used with the harmonic scalpel as "0" even though the range used was 0-28, and clips were used in 46% of patients. How then could the median be "0"?
- b) Dissection times of 36 and 39 minutes may not be significantly different, but since these times did not include preparation of the artery or closure of the incision, they are much slower than dissection with electrocautery (max. 15 minutes in my experience).
- c) An excellent way to relieve (or prevent) spasm is to ligate the artery at the wrist as soon as the skin incision is completed, so that the vessel's pulsation dilates it during harvesting until the proximal end is ligated as the last step. Was this technique used? If not, why?

Authors' Response by Creighton B. Wright, MD:

- a) The mean and the median of a sample are usually different. The mean is calculated as the sum of all observations ($x_1 + x_2 + \dots + x_n$) divided by the number (N) of observations. The median is the value at which 50% of all observations, when arranged in order of magnitude (smallest to largest), lie on either side of the value. If the number of observations is even, the median is the average of the two middle values. If the number of observations is odd, the median is the middle value.
Twenty-six patients contributed to the number of clips used in the HS group. The observations were: 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 4, 5, 8, 11, 11, 12, 14, 14, 19, 24, 28, and 28. The mean number of clips used was 7 ($178/26=6.85$). The median is the average of the 13th and 14th observations. In this data set, both the 13th and 14th observation were 0, therefore the median is 0.
- b) The protocol and text of our study define dissection (harvest) time as "the time from radial artery skin incision to the final arterectomy." The authors would like to stress the overall condition of the conduit and not the time required to harvest the vessel.
- c) We obviously did not use the reviewer's ligation technique. However, I use this technique for harvesting the internal thoracic artery but still have spasm in the harvested artery with this method. Thus, I am not convinced that it is particularly helpful. In this study, the radial

artery was left attached and with circulating heparin until the last possible moment.

2. Editorial Board Member GX21 writes:

How was the study sample size determined? The variable of number of clips used is so different that fewer patients may have been needed.

Authors' Response by Creighton B. Wright, MD:

The sample size was calculated to detect rare adverse events, not differences in the number of clips used or procedure time. It was determined that 51 subjects were sufficient to detect an adverse event that occurs within a population at least 10% of the time.

3. Editorial Board Member NE55 writes:

Can the author specify the harvesting technique used? Was it indeed the pedicle technique? A conclusion of "success" based on only three angiographies being performed is inadequate without mentioning the functional status of the patients.

Authors' Response by Creighton B. Wright, MD:

Yes, we did use a pedicle technique in harvesting the radial artery. We included the vena comitantes and associated areolar tissue with the radial artery.

I agree that a conclusion of success as a function of only three angiographies is not particularly helpful. The functional status of our patients was such that there was no evidence of hypoperfusion secondary to graft spasm or technical inadequacy that might be manifested by perioperative infarction, low cardiac output, or recurrent chest pain.

4. Editorial Board Member DB515 writes:

The article gives a good description of how the radial artery can be successfully used, with a good overview of literature.

Maybe the HS should be compared to low level cautery rather than to the cold steel scalpel. We use the HS in endoscopic IMA harvest and have been quite satisfied. Others use cautery with good results. One of the main advantages of the HS in IMA harvest seems to be a reduction of spasm, and we have found that the flow in HS harvested IMAs is better than in cautery harvested ones. It would be interesting to compare flows in the two groups of radial arteries.

Authors' Response by Creighton B. Wright, MD:

We have never used cautery, low level or high level, to harvest the radial artery because we believe that the propensity of the radial artery for spasm may be aggravated by the use of cautery. Others, however, may feel quite comfortable with the use of electrocautery. We have become very comfortable with the use of the HS and believe that it causes less spasm than our technique of sharp and blunt dissection with the use of clips to control bleeding.

5. Editorial Board Member LO23 writes:

- a) This is a simple observational study comparing the use of the HS with standard surgery or electrocautery. The only significant difference—the number of clips used—reflects more the surgical technique (surgical dissection with application of Liga clips) than the need to place "additional clips" later to control bleeding. This fact was not specifically addressed. Were no additional clips placed on the radial pedicle after harvesting with either method?
- b) Were all radial artery harvests done by the same surgeon?
- c) Had any patients taken aspirin preoperatively or received any other anti-coagulant or anti-platelet agents in the previous three days? Was this information recorded and compared?

Authors' Response by Creighton B. Wright, MD:

- a) The distribution of clips used at different points in the procedure was not documented. Only the total number of clips used for the entire procedure was recorded, so there is no data to address this question.
- b) The procedures were completed by the two surgeons, principal investigators at their respective sites.
- c) The medications that patients received prior to the surgical procedure were not formally identified, nor was any analysis performed on medications taken by patients following the procedure. We try to specifically avoid operating on patients who are on antiplatelet drugs other than aspirin, particularly 2b3a anti-platelet drugs, as we have had problems with bleeding in patients who have taken them. In this group none of the patients had 2b3a agents. In emergent cases with patients on these agents, I generally will not use a radial conduit.