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MEDICAL DEVICES COMPANIES

# Study Summary

## New Harmonic scalpel versus conventional haemostasis in right colon surgery: a prospective randomised controlled clinical trial

Sista F, Abruzzese V, Schietroma M, et al. Dig Surg. 2013;30(4–6):355–361.

## Conclusion

HARMONIC™ ultrasonic device reduces operative time and blood and lymphatic loss, and allows satisfactory maintenance of protein storage, resulting in a lower incidence of complications and faster patient recovery following right colon surgery. For these reasons the HARMONIC™ ultrasonic device should be used routinely in colon surgery

## Study Aim

To evaluate the effectiveness and safety of the HARMONIC™ ultrasonic device compared with conventional haemostasis in open right colon surgery.

## Methods

- In a double-blinded randomised controlled trial, 211 consecutive adult patients undergoing hemicolectomy in open surgery for cancer of the right colon were recruited at an Italian hospital and randomised to either:
  - HARMONIC™ Focus Long Curved Shears (Ethicon Endo-Surgery Inc., Cincinnati, USA; n=108)
  - Conventional haemostasis (CH; n=103), where haemostasis was performed using resorbable sutures or monopolar/bipolar diathermy
- All patients were followed up with outpatient visits at 2 weeks, 6 months and then every year after surgery
- Intention-to-treat analysis was conducted using the Student t test or Mann-Whitney U test

All procedures were performed by a team of 4 consultant surgeons trained in colorectal cancer resections and who adopted the principles of enhanced recovery programs

### Primary Endpoints:

- Operative time

### Additional Endpoints:

- Drainage volume, length of hospital stay, time to resumption of normal diet and bowel function, complications and blood biochemistry

# Results

## Operative Time

Operative time for hemicolectomy was shorter with HARMONIC™ versus CH.

**▼28 minutes**
shorter with HARMONIC™ (p<0.05)

## Complications

HARMONIC™ significantly reduced the rate of complications compared to CH (p<0.05).

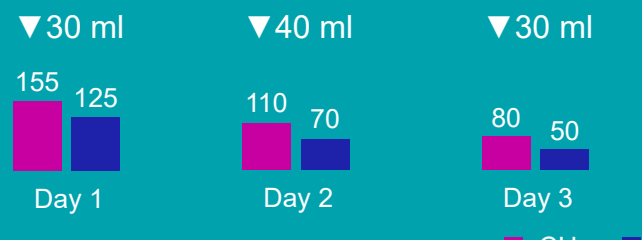
| ▼14.0% | ▼7.9% | ▼4.9% |
|---|---|---|
| Overall complications | Wound complications | Intra-abdominal sepsis |

Rates of anastomotic leak and postoperative ileus were similar between the HARMONIC™ and CH groups (3.7% vs 4.8% and 1.8% vs 1.9%, respectively).

## Enhanced Recovery

HARMONIC™ led to rapid patient recovery.

HARMONIC™ resulted in a significant reduction in postoperative drainage volume (ml) on days 1, 2 and 3 compared to CH (p<0.05)




HARMONIC™ reduced length of hospital stay (days) compared to CH (p>0.05)


CH HARMONIC™

- The HARMONIC™ group had a significantly higher serum concentration of albumin compared to CH postoperatively; improved protein maintenance may help to preserve patients' regenerative capacity
- Serum CRP levels remained stable and similar between groups
- Time to resumption of normal diet and bowel function was 4 days for both groups

# Additions

Other studies were highlighted in which HARMONIC™ was found to produce minimal damage to the surrounding tissues because the ultrasonic energy produced minimal heat. This resulted in low complications and enhanced patient recovery.[1–3]

**References:** 1. Pogorelić Z, Perko Z, Družijanić N, et al. How to prevent lateral thermal damage to tissue using the harmonic scalpel: experimental study on pig small intestine and abdominal wall. Eur Surg Res 2009; 43: 235–240. 2. Perko Z, Pogorelić Z, Bilan K, et al. Lateral thermal damage to rat abdominal wall after harmonic scalpel application. Surg Endosc 2006; 20: 322–324. 3. Sista F, Schietroma M, Ruscitti C, et al. New ultrasonic dissector versus conventional hemostasis in thyroid surgery: a randomized prospective study. J Laparoendosc Adv Surg Tech A 2012; 22: 220–224.

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