

Comparison of surgical outcomes using Gyrus PK vs Ligasure at total laparoscopic hysterectomy: a randomized controlled trial

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Introduction

Advanced vessel sealing devices are widely used in laparoscopic surgery.

Evidence suggests that these devices have decreased blood loss and shorter operative times compared to conventional bipolar electrocauterization^{1,2}.

There remains a lack of adequately powered trials comparing laparoscopic energy sources and devices in the clinical setting, especially in gynaecology³.

Objectives

To compare the outcomes at total laparoscopic hysterectomy (TLH) using either Gyrus PK or LigaSure.

To compare surgeons' evaluations of the devices.

Methods

- Single-blinded RCT
- Single site
- 4 experienced surgeons and teams

Inclusions:

- Women requiring TLH for any benign condition
- ≥35 years old

Exclusions:

- Suspected malignancy or pregnancy
- Uterus ≥14 week size based on ultrasound or clinical assessment
- TLH deemed not most appropriate method for hysterectomy

References

Gyrus PK (5mm LYONS™ 33cm dissecting forceps)	LigaSure (LS 1500V 5mm laparoscopic 37cm sealer/divider)
Pulsed radiofrequency energy at ultra-low voltage	Pressure and high current-low voltage energy
Proximal thrombus to seal blood vessels	Denatures collagen and elastin to create permanent fusion zone between blood vessel walls
Audio feedback as tissue impedance increases >> Surgeon controls device	Audio feedback as tissue impedance increases >> Automatic discontinuation of energy
Serrated two-tier jaw with fine, curved tip	Integrated cutter

Results

69 women recruited of whom 64 were included in the study

Surgical outcomes:

Outcome	Gyrus PK (n=33)	LigaSure (n=31)	Ratio (95% CI)	P-value
Time to Haemostasis (min) Log transformed*	74.39 (±17.4) 73.6	63.81 (±19.6) 62.1	1.2 (1.0, 1.3)	0.011
Total Operative Time (min) Log transformed*	114.12 (±20.3) 73.6	100.16 (±25.0) 62.1	1.2 (1.0, 1.3)	0.017
Estimated Blood Loss (ml)*	32.9 (18, 60.2)	36 (17.6, 73.6)	0.9 (0.4, 2.3)	0.84
Post-operative Opioid Use to Day 1 (mg)†*	106.7 (88.1, 129.1)	97.6 (78.0, 122.2)	1.1 (0.8, 1.5)	0.54
Length of Stay (days)*	3.8 (3.6, 4.1)	3.7 (3.4, 3.9)	1.0 (0.9, 1.2)	0.37
Complications	2	1		
Conversions	1	--		

* Log transformed data as continuous variable not normally distributed

† Oral morphine equivalent daily dose

Surgeons' evaluations:

Device evaluation	Gyrus PK	LigaSure	P-value
Sealing ability	4.2	4.09	0.46
Tissue release	4.28	3.86	0.02
Grasping ability	3.92	3.45	0.02
Dissection ability	4.6	3.5	<0.01
Control precision	4.52	3.68	<0.01
Comfort	4.2	4.18	0.88
Learning curve	4.08	3.86	0.11

Discussion/Conclusion

TLHs performed with LigaSure were 10 minutes faster in Time to haemostasis and Total operative time, consistent with current literature comparing the two devices. This is statistically significant but not clinically significant. There were no other statistically significant differences in the surgical outcomes between the devices.

Based on Surgeons' Evaluations, Gyrus PK performed better than LigaSure.

The main limitation to this RCT was the small study sample size. It was powered to calculate time difference, but not for surgical complication rates.

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2. Ou CS et al. Total laparoscopic hysterectomy using multifunction grasping, coagulating, and cutting forceps. J Laparoendosc Adv Surg Tech, 2004, 14(2):67-71
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