Randomised controlled trial on pre operative withdrawal Vs no pre operative withdrawal of Aspirin in laparoscopic inguinal hernia surgery (interim report)

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INTRODUCTION

- The incidence of inguinal hernias requiring routine surgical repair continues to rise amongst the ageing population worldwide.
- Cerebrovascular and cardiac comorbidities requiring utilisation of regular antithrombotic therapies remains prevalent in this population.
- Currently no consensus exists on perioperative management of antiplatelet therapy in patients who undergo an otherwise low surgical risk elective laparoscopic hernia surgery.

AIM

The aim of this study is, therefore, to investigate the safety, benefits and risks of withdrawing aspirin preoperatively versus non withdrawal of aspirin preoperatively in patients undergoing laparoscopic inguinal hernia repair.

METHODS

- Prospective, randomized controlled trial
- Duration: 2015 to present
- Study population: 96 patients undergoing laparoscopic TEP (Total Extra-Peritoneal) inguinal hernia repair under general anaesthesia
- Patients who are unfit for general anaesthesia, have obstructed / strangulated hernias will be excluded from this study.
- Randomized into 2 groups by coin toss method: preoperative aspirin cessation and no preoperative aspirin cessation
- Standardised surgical lap TEP technique, performed by principal surgeons of the study
- Follow-up up to 6months (1 week, 2 weeks, 1 month, 3 months post op)
- Data collected on bleeding, thromboembolic complications, wound infections, hematoma/seroma formation, length of hospital stay, postoperative pain, use of analgesics, return to work and recurrence.

METHODS (CONTD.)

Patient Demographic Variables

		Aspirin Continued (n = 30)	No-Aspirin (n = 35)	
Gender	Male	28	35	p = 0.2091
	Female	2	0	
Age (Mean, SD, Range)		66.13 ± 11.02 (43 – 81)	69.57 ± 8.20 (49 – 86)	p = 0.1551
BMI		23.6 ± 3.65 (18.4 – 30.7)	24.0 ± 3.44 (17 – 30.6)	p = 0.6608
ASA	II	19	21	p = 0.8041
	III	11	14	
Type of Hernia	Primary	29	32	p = 0.6177
	Recurrent	1	3	

Comparison of Operative Findings

		Aspirin Continued (n = 30)	No-Aspirin (n = 35)	
Surgical Technique	TEP	25	31	p = 0.7217
	TEP+ / mTEP	5	4	
Duration of Surgery		87.55 ± 17.41 (28 – 157)	87.92 ± 32.66 (70 – 114)	p = 0.9642
Unilateral vs Bilateral	Unilateral	10	9	p = 0.5886
	Bilateral	20	26	
	Total Hernia	50	61	
Type of the defect	L	42	49	p = 0.8046
	M	48	42	p = 0.0002
	F	10	16	p = 0.5039
	Multiple	33	39	p = 0.8443
	Other	0	0	p = 1.0
Mean defect size		1.62 ± 0.82 (1 – 3)	1.55 ± 0.74 (1 – 3)	p = 0.515

METHODS (CONTD.)

Comparison of Outcome Variables

		Aspirin Continued (n = 30)	No-Aspirin (n = 35)	
Wound site bruising before discharge		3	3	p = 1.0
Hematoma before discharge		1	1	p = 1.0
Duration of admission (Days)		0.9 ± 0.61 (0 – 2)	1.2 ± 0.63 (0 – 3)	p = 0.0567
Stay in ICU / SHD		0	3	p = 0.2428
30 Day readmission		0	0	p = 1.0
VAS at discharge		0.57 ± 0.9 (0 – 3)	0.86 ± 1.09 (0 – 4)	p = 0.2498
Thromboembolic complications		0	0	p = 1.0
30 Day mortality		0	0	p = 1.0
Other post-op complications	Seroma	6	11	p = 0.3984
	Hematoma	2	1	p = 0.5913
	Wound infection	0	1	p = 1.0
	Recurrence	0	0	p = 1.0
	Chronic pain	0	0	p = 1.0
Follow-up (Days)		189.23 ± 27.73 (180 – 299)	192.60 ± 0.58.21 (180 – 513)	p = 0.7731

RESULTS

- All post-operative hematomas and seromas were managed conservatively and all of them recovered well
- Nil reported recurrence in current follow up
- Nil 30 day readmissions or mortalities encountered in either group

CONCLUSION

The preoperative non withdrawal of aspirin in patients undergoing laparoscopic inguinal hernia repair does not have a statistically significant difference in comparison to the withdrawal of aspirin in terms of adverse perioperative and postoperative bleeding or thromboembolic complications at the time of this interim report.