

FOLLOW-UP OF RANDOMIZED CONTROLLED TRIAL OF GASTROSTOMY WITH MEDICAL TREATMENT *VERSUS* GASTROSTOMY WITH FUNDOPLICATION IN CHILDREN WITH NEUROLOGICAL IMPAIRMENT

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Aim of the Study: To investigate whether medical management of gastro-oesophageal reflux (GOR) provides similar results to fundoplication in neurological impaired (NI) children requiring a gastrostomy

Methods: With appropriate ethical approval, a follow-up of a randomized controlled trial (RCT) was performed. Children with NI requiring gastrostomy and treatment for severe GOR defined by combined pH/impedance study had been randomized to either: laparoscopic gastrostomy with maximal medical treatment (group A; 15 children) or laparoscopic gastrostomy and Nissen fundoplication (NF) (group B; 13 children). Failure was defined as need for a second procedure following the allocated primary procedure. Data are reported as median (range) or number of cases and were analyzed by Mann-Whitney U test and Fisher's Exact Test.

Main Results: Age at randomization was 20 months (3-92); age at surgery was 21 months (5-96). Associated anomalies in addition to NI were present in all children. Deaths in each group were secondary to the primary medical condition and not associated with GOR. Follow-up in surviving patients was 45 months (25-71). Main results are presented in the table. Overall, 8 (36%) survivors required a second procedure to control GOR but there was no difference in re-intervention rate between the groups. One child in group A and 2 children in group B required a third procedure (gastro-jejunostomy) for severe GOR after failed second procedure.

Conclusion: This follow-up study indicates that gastrostomy with medical treatment and gastrostomy with fundoplication in children with GOR and neurological impairment provide similar long-term results with an overall reintervention rate of 36%. A large multicentre trial may help clarifying if gastrostomy with medical treatment should be considered as the first line of treatment in children with neurological impairment and significant GOR.

Table

	Group A	Group B	P value
Second procedure	4 (Nissen fundoplication) 1 (Gastro-jejunostomy)	3 (redo-Nissen fundoplication)	0.4
Third procedure	1 (Gastro-jejunostomy)	2 (Gastro-jejunostomy)	0.6
Change in weight Z-score	+0.03 (\pm 0.46)	+0.86 (\pm 0.86)	0.4
Deaths	3	2	1.0