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## Postoperative gastrostomy site leakage correlated to the dimension of the gastrostomy button in children

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### Abstract

The laparoscopic placement of gastrostomy buttons for feeding tubes is the preferred method of gastrostomy in children with feeding requirements. This intervention often leads to some minor postoperative problems, including gastrostomy site leakage. The aim of our study was to test the hypothesis that the postoperative leakage after a video-assisted gastrostomy is correlated to the dimension of the gastrostomy button used during the operation. Included in the study were 164 children with nutritional problems who consecutively underwent surgery; they had a video-assisted gastrostomy operation. In the first 87 children, a 14 French (Fr) gastrostomy button was used and in the last 77, a 12 Fr button was used. After the operation, the children were followed up prospectively and all complications were documented according to the study protocol.

Our study revealed a significant correlation between the dimension of the gastrostomy button and the postoperative leakage at the gastrostomy site. The rate of leakage at the gastrostomy site was 37% in the children who had 14 Fr gastrostomy buttons compared to 18% ( $P=0.038$ ) in the children who had 12 Fr gastrostomy buttons, during the first six months postoperatively. These results suggest that postoperative gastrostomy site leakage was significantly higher in children who had 14 Fr gastrostomy buttons than in those with 12 Fr buttons. To avoid this complication, 12 Fr gastrostomy buttons should be used.

### Introduction

Primary laparoscopic placement of gastrostomy buttons for feeding tubes is a safe and simple technique and the preferred method of gastrostomy in children.<sup>1</sup> The dimensions of the gastrostomy buttons used have decreased over time from 24 French (Fr) to 12 Fr. The question arose whether the reduction in dimension of the gastrostomy button leads to fewer postoperative complications and if we should demand even smaller devices (e.g. 8 Fr)

from the industry. This study was undertaken to test the hypothesis that a reduction of the dimensions of the gastrostomy buttons leads to fewer postoperative complications. We are not aware of any similar reports in the literature.

### Materials and Methods

A heterogeneous sample of 164 children, who consecutively had the standardized laparoscopic placement of a gastrostomy button<sup>1,2</sup> under general anesthesia during the period from January 2005 to August 2009, were included prospectively and followed up. The first 87 patients received a 14 Fr gastrostomy button in the stoma while the remaining 77 received 12 Fr gastrostomy buttons in their stoma. The length of the buttons used was 1.2 cm or less in 47% of the children and 1.5 cm or more in 53% of the children, with no significant difference between the groups. We used the MicKey® gastrostomy button (Ballard Medical Product, UT, USA). Twelve Fr (1 Fr = 1/3 mm) buttons have the diameter of 4.0 mm compared with 4.7 mm of the 14 Fr buttons, making the cross-sectional area ( $\pi \times r^2$ ) of the 12 Fr button 72% of that of the 14 Fr button.

The indications for a gastrostomy were nutritional problems that persisted for more than six months,<sup>3,7</sup> in children with severe diseases. There were no contraindications to surgery in any of the cases. A barium meal had been performed in all patients to rule out a gastric outlet obstruction. All patients were evaluated clinically for gastro-esophageal reflux disease (GERD) before the operation and none had the indication for concomitant surgery for GERD.

All the children were followed-up prospectively during the first postoperative days in the hospital and at one and six months after the operation. The endpoint of the study was six months after the surgery. Additional follow-ups were performed any time at the request of the child's guardians. All complications were documented according to a standardized protocol by a specially trained nurse. The postoperative complications requiring treatment that we registered included:

- granuloma resulting in intervention, such as cauterizations;
- infection requiring antibiotics; and
- a leakage that required further management, including a change to a new button with a different length or size, or a change of volume in the balloon of the button, or frequent (greater than two times a day) change of dressings.

This study included follow-up of only the patients operated on routinely. The protocol was designed to meet the legislative documentation required in the country of ori-

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Key words: gastrostomy, laparoscopy, children, gastrostomy button.

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gin. Formal approval from the ethical committee (D nr 2010/49) was given. The informed consent of the children's guardians was obtained. This work was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

### Statistical considerations

Based on our previously published data using the frequency of postoperative complications as the primary endpoint, a sample size of 75 patients and 75 controls was calculated as sufficient to perform a t-test, obtaining a significant difference when the mean difference is 0.3. The alpha level for rejecting the null hypothesis of mean difference equal to zero is 5% and the power is above 80%. The Mann-Whitney two-tailed U-test was used. All statistical computations were made using SPSS version 15 (SPSS, Inc., Chicago, IL, USA). A value of  $P < 0.05$  was considered significant.

### Results

There were no serious surgical complications, such as perforation of hollow organs or bleeding. In the immediate postoperative period, no wound or intra-abdominal complications occurred. There were no re-operations owing to adhesions or leakage. The patients' demo-

graphic data and diagnoses are summarized in Table 1. The number and types of complications in the two groups correlated to the dimension and length of the gastrostomy button are described in Table 2. There was a statistically significant difference in the postoperative complication of gastrostomy site leakage found between the two groups studied. The problems of leakage were significantly higher in the 14 Fr gastrostomy button group. We found no correlation between the length of the gastrostomy button and the postoperative problems of leakage (Table 2).

## Discussion

When correlating the incidence of minor complications in these groups of infants and children with different diagnoses and sizes of gastrostomy buttons, we found a significant difference between the gastrostomy site leakage and the size of the gastrostomy buttons. These findings support our hypothesis that the size of the gastrostomy button influences the complications of leakage through the gastrostomy site. Therefore, we can claim that the use of a gastrostomy button with smaller dimensions reduces the number of postoperative gastrostomy site leakages. However, both the 12 Fr and 14 Fr buttons are very small and a greater leakage rate may be seen if we compare them with buttons of larger dimensions; for example, 24 Fr buttons with an area four times that of the 12 Fr buttons. Data from our previous publications where gastrostomy buttons with larger dimensions were used showed that large gastrostomy buttons were associated with more postoperative complications.<sup>3,4,6</sup> The complications from the gastrostomy button in this study were recorded prospectively, and included local infections and mechanical problems with pain and leakage. The same types of complications were encountered in both groups and were similar to those in our previous experience.<sup>3,4,6</sup> When using 24 Fr and 16 Fr gastrostomy buttons of the same type as we used in this study, we demonstrated a higher frequency of postoperative complications.<sup>5</sup>

It is unknown whether even smaller gastrostomy buttons (e.g. 8-10 Fr buttons) may decrease the postoperative gastrostomy site leakage further. In addition to the size of the gastrostomy buttons, there are other ways to decrease the leakage rate. For example, changes in the operative technique for constructing a gastrostomy may lead to a gastrostomy closing more tightly around the gastrostomy button; or the path of the gastrostomy may be laid in an oblique way through the abdominal wall, thereby lengthening the gastrostomy and leading to a tightening of the gastrostomy channel with increased abdom-

**Table 1. Demographic data and the diagnosis of the children.**

Gastrostomy button dimension	12 Fr	14 Fr	P*
Number of patients (male/female)	77 (36/41)	87 (41/46)	
Age in years, median (range)	1.1 (1 mth-14 yr)	1.7 (2 mth-14 yr)	
Mean $\pm$ SD	2.5 $\pm$ 3.1	3.1 $\pm$ 3.8	0.054
Weight in kg, median (range)	9.0 (3.6-39.4)	9.4 (4.0-41.0)	
Mean $\pm$ SD	10.4 $\pm$ 6.4	11.9 $\pm$ 7.8	0.212
Z-score** median (range)	1.9 (-7.1- -1.9)	-2.1 (-6.0-1.3)	
Mean $\pm$ SD (range)	-2.1 $\pm$ 1.8	-2.2 $\pm$ 1.6	0.195
Diagnoses	12 Fr	14 Fr	
	N = 77	N = 87	
Cerebral palsy	35 (46%)	36 (42%)	
Malignancy	3 (4%)	7 (8%)	
Cardiac anomaly	13 (17%)	15 (17%)	
Metabolic disease	8 (10%)	14 (16%)	
Syndrome	14 (18%)	9 (10%)	
Gastrointestinal malformations	4 (5%)	6 (7%)	

\*The Mann Whitney U-test was used for statistical calculations. \*\*These figures are also expressed as weight-for-age Z-scores. Calculated as (actual weight - mean weight)/standard deviation according to the nationally standardized weight curves.

**Table 2. Complications of a gastrostomy button, button dimension, and button length.**

Button dimension	12 French	14 French	P*
	N = 77	N = 87	
Leakage	14 (18%)	32 (37%)	0.038
Granuloma around the gastrostomy**	22 (29%)	35 (40%)	0.194
Infection leading to use of antibiotics	20 (26%)	19 (22%)	0.648
Button length	$\leq$ 1.2 cm	$\geq$ 1.5 cm	
	N = 78	N = 86	
12 Fr / 14 Fr	46/32	31/55	
Leakage	20 (26%)	26 (30%)	0.621
Granuloma around the gastrostomy**	23 (29%)	34 (40%)	0.264
Infection leading to use of antibiotics	23 (29%)	16 (19%)	0.226

\*The Mann Whitney U-test was used for statistical calculations. \*\*These disappeared during the first six months. In 7% of the children the granuloma appeared again, sometimes six months after the operation.

inal/stomach pressure, thus decreasing the leakage rate.

Serious complications, such as gastro-colic or gastro-intestinal fistulas, bleeding, leakage into the peritoneal cavity, peritonitis, dislodgement or occlusion of the gastrostomy button, were not seen in our patients. The problems met by the infants and their parents and summarized in this study are reported in the literature rarely, although they are well known and often seen after a surgical gastrostomy or percutaneous endoscopic gastrostomies (PEG). These problems were not life threatening and did not affect the lives of the infants and their families. However, they should be taken into account in patient counseling and when discussing the need for a gastrostomy in individual patients.

In the method described here as well as in the open surgical procedure, the gastrostomy button is put in place directly, eliminating the need for a later change of the button, as is the case after PEG where this is usually done after six weeks and may demand anesthesia or sedation for the child.

In spite of the fact that the data presented in this study were gathered prospectively, there are weaknesses and bias in the study. Firstly, the operative interventions were performed by seven pediatric surgeons, and therefore there are small individual variations in the performance of the operative intervention. Secondly, although the follow-up evaluation at one and six months postoperatively was in the hands of two professionals at the hospital, there is a place for small individual variations in the

reporting of the registered complications. Thirdly, the patient group was heterogeneous with differences in diagnosis and age, and the number is relatively small. Fourthly, the important difference in the patients' state of nutrition<sup>8</sup> was not taken into account in these small groups of children when the cohort had been split into subgroups. Nevertheless, we concluded that a reduction of postoperative gastrostomy site leakage may be gained with the use of gastrostomy buttons with a smaller dimension.

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