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Is image guidance accurate in children sinus surgery?

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ABSTRACT

Objectives: To compare the precision of the calibration of a 3D navigation system for endoscopic sinus surgery in children and adults. To compare the complication and calibration failure rates of the system in both populations.
Methods: The precision of the calibration of the Stryker navigation system (Stryker Neuronavigation ENT 2.0 Software) was found in the charts of children and adults operated on for various nasosinusal procedures between May 2008 and February 2013 in a tertiary care center. Demographic characteristics and complication rates were also noted.
Results: Thirty-eight adults and 21 children were included in the study. No statistically significant difference was found between the two groups with an identical mean precision of 0.7 mm ($p = 0.90$). The rate of precision unreliability and calibration failures was not statistically different between the two groups (14% children vs 5% adults). No major complications occurred in both groups ($p = 1.00$). No demographic characteristic predicted a failed calibration (height, weight, BMI, age).
Conclusion: The Stryker image-guided system can provide a precision level that is equivalent in both children and adults. This study also demonstrated an absent/low complication rate respectively for children and adults post endoscopic surgery.

1. Introduction

Image-guided navigation systems have been used increasingly within the last decade in many surgical fields such as orthopedics and neurosurgery [1,2]. They allow intraoperative spatial orientation based on the matching of preoperative radiological images with the operative anatomic sites [2]. They are extremely useful in areas with difficult exposition and where a lack of precision in the surgical procedure can be dangerous for the patient. This is especially true in endoscopic sinus surgery in which a few millimeters make the difference between a successful procedure and significant complications such as an orbital penetration or a skull base perforation with a cerebrospinal fluid leak. Navigation systems were widely used in the adult population before being applied to the pediatric age group. However, in nasal and sinus surgery, no studies so far have compared the precision and safety of these systems in a pediatric versus adult population. The main goal of this study was to compare the precision of the Stryker's Navigation System used for endoscopic nasal and sinus surgery in the pediatric versus adult population. As secondary endpoints, we compared the complications rate and calibration failures rate of the system in both populations.

2. Methods

This retrospective study took place at a tertiary care center: le Centre Hospitalier Universitaire de Québec. We included all the pediatric and adult patients operated on by the senior author (JEL) for an image-guided naso-sinusal procedure between May 2008 and February 2013. All surgeries were performed with the Stryker Navigation System (Stryker NeuroNavigation ENT 2.0 Software) – an optically guided system – with either the standard digitalized adult mask or the pediatric headband. At the beginning of the procedure, the system was calibrated and the precision in millimeters was obtained from the computer screen. The surgeon tested the accuracy by moving the seeker to two cutaneous surface landmarks (external canthus) and along the middle turbinate on

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each side. In each chart, we looked for the precision as determined by the navigation system. A calibration failure was defined as the failure to reach a calibration (discrepancy between the value and the surgeon's findings) or a precision greater than 1 mm. The adult and children data were first compared. The children were also divided in three groups according to their age to determine if the growth of the head and the sinuses had any impact on the accuracy of the navigation system. For data analysis, we used the Student's *t*-test to compare the precision between the two groups. The Fisher exact test was used for the rate of calibration failures and complications. A Pearson's correlation was performed to compare the rate of failures to the patient's demographics characteristics. Values were considered statistically significant if the *p*-value was under 0.05.

3. Results

A total of 152 sinus endoscopy charts were reviewed of which 91 were operated with image guidance. Fig. 1 shows that 32 patients had to be excluded for various reasons. The remaining 59 patients were divided in two groups according to their age (21 patients <18 years old and 38 patients ≥18 years old). In the adult age group, the mean age was 45 years (20–81 years) and the male–female ratio was 1:1 (Table 1). In the pediatric age group, the mean age was 9 years (47 days to 17 years) with about the same male–female ratio (1.1:1). The detailed demographics, surgical indications and procedures of the pediatric patients charts are shown in Table 2. The main indication for surgery was recurrent and chronic sinusitis in the two groups, with respectively 57% and 74% in the pediatric and adult population (Fig. 2). As for the navigation protocol, both groups presented similar results (Table 3). The children's mean precision of 0.7 mm (0.3–1.0 mm) was identical to adult's mean precision of 0.7 mm (0.4–1.0 mm) ($p = 0.90$). When further divided by age, children had similar precisions with mean respective values of 0.8 mm, 0.6 mm and 0.7 mm for patients between 0 and 6, 6 and 12 and 12 and 18 years old ($p = 0.18$). The image-guided system's reliability was inadequate or the system failed to calibrate in three children and two adults (14.3% and 5.3%, respectively, $p = 0.34$). Two of the reliability issues happened in the subgroup 0–6 years old and the other in the 6–12 years, without any statistically significant difference between all groups ($p = 0.11$). No relation was found between the pediatric population height, weight and body mass index (BMI) and the proportion of inadequate or failed calibration (*p*-values of 0.24, 0.28 and 0.50, respectively). The digitalized mask was used in all adults' surgeries and 20 out of 21 pediatric surgeries (95%). The digitalized headband was used for the remaining child because the mask was too large. No complications occurred in the children group (0/21) and a minor complication occurred in only one adult (2.6%).

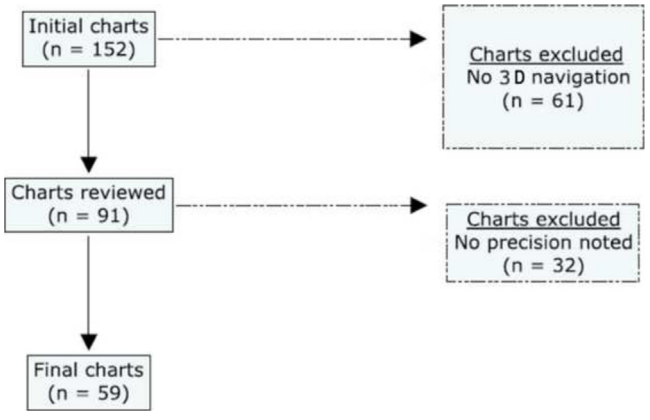

Fig. 1. Patient flow.

Table 1
Clinical data of patients.

	Children	Adults	*p* values
Age	9 (47 days–17 years old)	45 (20–81 years old)	<0.0001
Male:female	1.1:1	1:1	0.43
Weight (kg)	32 (5–67)	71 (47–120)	0.44
Height (cm)	130 (64–170)	168 (161–182)	0.01
BMI (kg/m^2)	18 (13–25)	25 (20–35)	0.04

4. Discussion

Image guidance is increasingly being used although the equipment remains extremely expensive. Because of their smaller size, children's endoscopic procedures are often more difficult than their adult counterpart. It is even more obvious in complex surgical procedures such as pituitary adenoma surgery with the trans sphenoid approach [3]. Image guidance can be used on a continuous way or at some critical points of the procedure. In our case, the navigation system was used as needed during the surgery to confirm that both visual landmarks and images on the guidance system corresponded one to each other.

To the best of our knowledge, this is the first study to compare the accuracy of the calibration between a pediatric and an adult population. We found identical results for precision in both the pediatric and the adult populations (0.7 mm vs 0.7 mm, $p = 0.90$) (Fig. 2). These values are similar or inferior when compared to other pediatric or adult studies [2,4] (Table 4). Furthermore, when we looked at subgroups of children according to their age, we had similar results between all groups (precision from 0.6 to 0.8 mm) (Fig. 3). These results support the usefulness of 3D navigation even in a very young population in whom all the anatomic structures are smaller and complications may be more likely to occur. Precision was still adequate for deeper lying structures such as sphenoid sinus or choanal atresia surgeries (Table 4). Adequate precision was obtained for all age groups. Even if there is very little data in the literature on the average accuracy in children, Lusk et al. [5] stated that one should strive for an accuracy of at least 1.5 mm in children.

Intraoperative navigation systems have been classified into either optical or electro-magnetic navigations systems. Precision of both systems seems to be similar. In our study, we used the Stryker NeuroNavigation ENT 2.0 Software, which operates on an optical system. Table 2 describes the main characteristics of the patients in the pediatric group, including surgical indications and calibration failures. The overall reliability of the Stryker image guidance system has been excellent with calibration failures happening in three children and two adults (14.3% and 5.3% respectively, $p = 0.34$). No statistically significant difference was found between the children subgroups. However, two failures occurred in very young patients (<3 months), but were not statistically significant ($p > 0.05$). We think the main reason for the failures in both cases was a technical problem with the system that was eventually solved. We used the same size of masks for both groups although the company clearly states that the masks were not designed to be used in children. No predictive factors for the calibration failures were found to be statistically significant.

Other than its retrospective process, our study has known limitations. The surgeon was not blinded about the age of the patients. We also had to exclude 32 patients from the cohort because their operative report mentioned the use of the navigation system but the precision of the calibration process was not