MINI HEALTH TECHNOLOGY ASSESSMENT

(Note: A mini HTA report consists of two parts. The first is completed by the applicant at the time the new technology is requested. The second consists of a commentary and possibly additional evidence provided by TAU)

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Balloon Catheter Dilation for Chronic Rhinosinusitis

PART I: Request for HTA (Completed by applicant)

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Technology (Name, Description, Purpose)

Acclarent Balloon Sinuplasty.

Similar to balloons in angioplasty and other areas, these are relatively new instruments to rhinology practice that allow symptomatic and medically refractory patients with narrowed or obstructed sinuses to be dilated in an office setting under local anesthesia, avoiding the need for general anesthesia for the patient and operating room time and resources for the hospital.

Has it been used at the MUHC? What is the alternative?

It has been trialed in the operating room by myself, at no charge from the company, on a total of 4 patients with good results and no complications. The alternative is traditional endoscopic sinus surgery in the operating room under general anesthesia.

Health benefits

Relief of acute and/or chronic sinusitis symptoms such as pressure pain, rhinorrea, and post-nasal drip; reduce the need for antibiotics, their associated side-effects, and the likelihood of antibiotic resistance; avoidance of general anesthesia; avoidance of complications of acute sinusitis.

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Risks/complications
Pain, bleeding, unsuccessful dilation or postoperative scarring

Unit costs (Direct costs of items requested)
Between $1090 to $1365, depending on the number of dilations done.

Usage (Quantity of drugs/expendables or number of procedures per year)
Approximately 3 to 5 patients per month.

Impact on hospital services (Bed usage, OPD, Etc)
The principal impact I envisage is a better use of operating room time, with a shorter wait time for both more complex cases in the OR and smaller cases to be done in the clinic with the help of this new technology. Since patients will only receive local anesthesia without any sedation, monitoring would be limited. I would require no additional resources for my clinic, as patients would be scheduled at the end of the day, and a single clinic nurse could assist me.

Resource Person/Expert at MUHC
Denis Gaumond

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PART II: Additional comments of Technology Assessment Unit

Completed by: Ioana Nicolau and Nandini Dendukuri

Background:

Balloon catheter technology for dilating the sinus ostia in patients with chronic rhinosinusitis was approved by the Food and Drug Administration (FDA) in the United States in 2005[1]. It is a minimally invasive procedure that alters the anatomy of the paranasal sinus ostia without removing tissue or bone, while preserving the mucosa[2]. The current standard treatment is functional endoscopic sinus surgery (FESS), a surgical approach that involves the removal of tissue and bone to dilate the sinus passages.

The balloon catheter sinuplasty (BCS) system, developed by Acclarent inc., includes the balloon catheter and a fiber optic guide wire[3]. The lighted guide wire is used to confirm sinus access and help balloon placement[3]. After the guide wire is placed, the balloon catheter is passed over it and inflated in the appropriate position[3]. The BCS system has largely been used as an adjunct to FESS in an OR setting under general anesthesia. It has only recently been used in an office setting under local anesthesia.

Methods: A systematic literature search was carried out using Pubmed, the health technology assessment (HTA) databases INAHTA, CADTH, NHSCRD, INESSS, and the Cochrane Library. The following key words were used: ("balloon" AND "sinus*"). Bibliographies of articles were also scanned for additional articles. The search was limited to articles on human subjects, published in English, between 2005 to August 22, 2012. One author (IN) carried out the literature search. Articles reporting on efficacy, effectiveness, safety or cost-effectiveness of balloon sinuplasty for chronic rhinosinusitis (CRS) were retrieved. We only selected studies of the Acclarent system with a sample size of 10 or more patients. Both authors reviewed the selected articles.

Results:

Balloon sinuplasty in a clinic setting

Only one multi-centre study of 37 patients (59 sinuses) evaluated the use of the BCS system in a clinic setting under local anesthesia[4]. It was sponsored by Acclarent. In order to test feasibility in a broadly representative population, patients with nasal polyposis and prior FESS were included. The types of sinuses treated were: maxillary 28 (47.5%), sphenoid 10 (16.9%) and frontal 21 (35.6%). The

technical success rate (i.e. rate of access and dilation of the targeted sinuses) immediately after the procedure was 89% (33/37) in terms of patients and 91% (59/65) in terms of sinuses. While 67% of patients (24/36) reported that pain during the procedure was of low intensity (pain scores of 0-2 on a 0-5 scale with 0=no pain), 12 patients (33%) reported more intense pain. Sino Nasal Outcome Test (SNOT-20) scores, which measure symptoms of CRS, showed clinically and statistically significant improvement after 24 weeks (based on N=26 patients) and after 52 weeks (based on N=21 patients). The Lund-MacKay score, which is based on a CT scan assessment, also showed significant improvement at 24 weeks. The mean Lund-MacKay score improved from 6.62 (standard deviation 3.80) to 2.79 (standard deviation 2.70). There were no serious adverse events. One patient needed to have a revision. The authors concluded that whereas the rate of technical success was acceptable for a first study of BCS in an office setting, further studies are needed to improve patient selection, to improve patient comfort via optimized anesthesia and to confirm safety.

Balloon sinuplasty in an OR setting

The majority of studies we identified evaluated the use of BCS in an OR setting under general anesthesia.

Evidence from Randomized Controlled Trials:

One double-blinded randomized controlled trial (RCT) of 32 patients by Plaza et al.[5] studied the effectiveness and safety of BCS during FESS in a group of patients with medically intractable CRS of the frontal sinuses. The study compared FESS+BCS of the frontal recess vs. FESS+frontal nasal drainage using a Draf 1/2a procedure. All patients had nasal polyposis and demonstrated total opacification of the affected r frontal sinus. This article was criticized for errors in reporting [5 6, 7]. Based on a rebuttal from the author [8] the results of this RCT are summarized below

	FESS + BCS	FESS + Draf 1/2a
Total number of opacified sinuses treated	26	24
Number of sinuses successfully dilated immediately after treatment (%)	21 (80.8)	22 (91.7)
Number of sinuses that remained patent at 12 months (%)	19 (73.1)	15 (62.5)

Resolution of sinus disease was observed more frequently in the BCS group, though this difference was not statistically significant. No major complications were

observed. Thus this study provided evidence, albeit in a small sample, that BCS is safe for use in treatment of CRS of the frontal sinuses and is comparable in effectiveness to FESS.

Evidence from observational studies**:**

The majority of studies evaluating BCS have been observational cohort studies. Eight such studies that met our selection criteria reported results were based on 1377 patients [9-16]. These studies have consistently reported that BCS is safe, with a very small risk of adverse outcomes such as cerebrospinal fluid leakage. In particular, one registry study [15] of 1036 patients reported no adverse events. These studies have also reported that following treatment with BCS there was an improvement in SNOT-20 scores and Lund-Mackay scores in all patients. The CLEAR study [9, 13, 16], with a follow-up of 2 years for 65* patients showed that symptom improvement on SNOT-20, and radiographic improvement on the Lund-MacKay score remained consistent from the 6 month follow-up onward [13]. The patient-specific revision rate was 9.2% (6/65) while the sinus-specific revision rate was 3.6% (7/195). However, a review by Batra et al. cautions that the high level of patency reported in the CLEAR study may not be achieved in all groups of patients[17]. A cohort study by Catalano and Payne of 20 frontal sinusitis patients (29 sinuses) with moderate or severe disease, reported radiographic improvement in only 48% of sinuses (14/29) [18]. One study attempted to measure pain associated with the BCS procedure by measuring the number of days post-procedure during which the patient took narcotic pain medication [10]. They found that the number of days was significantly lower in the BCS group compared to a group of FESS patients(mean=0.8 (standard deviation(SD)=0.72 vs. mean=1.34 (SD=0.99)).

Cost analysis:

The estimated procedure costs of the balloon sinuplasty procedure in the outpatient clinic and the operating room are presented in the Appendix. Based on input from Dr. Tewfik it is anticipated that 12-24 Balloon sinuplasty procedures could take place annually. He plans to use this procedure in a carefully selected sub-group of patients who need to have dilation of the maxillary or sphenoid sinuses, as well as the occasional postoperative frontal sinus stenosis. An estimated 5-6 procedures annually will be of the latter type. We have estimated the costs as follows:

- Standard FESS (functional endoscopic sinus surgery) procedure. The operating room and recovery room costs associated with FESS are approximately $1,348 per procedure.

* 34 patients underwent BCS and 31 patients underwent a hybrid procedure which included the use of both balloon catheters and traditional rigid instruments.

- Balloon Sinuplasty System. The average cost was estimated at $1,485 per procedure.
- Difference in cost: Thus, the cost of a clinic procedure with balloon sinuplasty would be comparable (roughly $137 higher) to a single operating room procedure.
- Post-operative frontal sinus stenosis. When balloon sinuplasty is used post-operatively the cost per procedure increases to approximately $2,748 ($1,348+$1400). In comparison, if the patient returns to the OR for a revision the overall cost would increase to $2,661 ($1,348+$2,626).
- Budget impact of Balloon Sinuplasty System: The estimated annual budget impact of procedures involving balloon sinuplasty would be $24,156-$39,912 ($8,910-$26,730 for 6-18 maxillary or sphenoid cases treated in a clinic setting + $16,488 for 6 post-operative frontal sinus stenosis cases).
- Budget impact of using FESS alone: The estimated annual budget impact of treating all cases with FESS would be $23,634-$39,390 ($7,878-$23,634 for 6-18 maxillary or sphenoid cases + $15,966 for 6 revision frontal sinus stenosis cases).

Conclusions

- Balloon catheter sinuplasty (BCS) is a relatively new procedure. It has been evaluated primarily in an OR setting, using general anesthesia, by studies using an observational design. These studies have generally concluded that it is comparable to the standard surgical approach for treating chronic rhinosinusitis in terms of effectiveness and safety. However, this remains to be shown in a randomized controlled trial that is sufficiently large.
- Only one small recent study has examined the feasibility of BCS in an office-setting, which is the main application of interest at the MUHC. Though the results of this study are promising, they remain to be confirmed in other studies. A majority of the patients studied (67%, 24/36) reported experiencing only a low intensity of pain.
- The per-procedure cost of balloon sinuplasty is comparable to, and perhaps slightly more expensive than, the surgical alternative despite the savings incurred from not using the operating room or recovery room. However, use of this procedure will free up OR time, which at the present time is a critical limiting factor at the MUHC.

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Recommendations.

- Given the acknowledged need for further research studies of BCS in an office-setting and the absence of a significant cost saving, this technology should be used only in a limited number of carefully selected cases. A registry of these cases should be maintained in order to record the effectiveness and safety of each procedure over a follow-up period of at least 1 year.

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https://secureweb.mcgill.ca/tau/sites/mcgill.ca.tau/files/muhc_tau_2012_68_balloon_sinuplasty.pdf

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Appendix: Cost Analysis of Balloon Catheter Dilation

Cost of the Balloon Sinuplasty System: These costs were obtained from the manufacturer, Acclarent Inc.One Balloon Sinuplasty System kit is used per patient. The purchasing price for the Balloon Sinuplasty System basic kit is $1,000. The basic kit includes a guiding light-wire (Luma Sentry), sinus guide catheter handle, balloon catheter, sinus irrigation catheter (Vortex) and the inflation device. In addition, a sinus guide catheter tip is used depending on the sinus being treated. The cost of a sinus guide catheter tip for maxillary and sphenoid sinuses brings the total cost to 1,400$ per patient.

Hospital resources: The standard FESS procedure requires 1 hour in the operating room (OR) plus 2 hours in the recovery room. Balloon sinuplasty performed in the clinic will require the help of a nurse for 1 additional hour over her regular schedule. The procedure in the clinic for one sinus lasts approximately 0.5 hours and topical anaesthetic is administered.

Hospital costs: The cost of pre-operation work-up was estimated at $35, the cost of an operating room is $883 per hour, the cost of a recovery room is $215 per hour and the cost of an otolaryngology (OTL) outpatient clinic visit is $170.6 per hour. These costs of personnel and supplies were obtained from Mr. Nicolas Robert, Department of Finance, MUHC. They are adjusted for inflation.

Table 1: Cost of balloon sinuplasty in outpatient clinic and operating room (assumed turnover 12 procedures per year)

	Office based procedure	**Functional Endoscopic Sinus Surgery (FESS)**
Single-use Balloon Sinuplasty System (two sinuses)	$1,400	--
Pre-operation work-up	--	$35
Operating room	--	$883 ($883 * 1 hour)
Recovery room	--	$430 ($215 * 2 hours)
OTL outpatient clinic	$85 ($170.6 *0.5 hours)	--
Cost per procedure	$1,485	$1,348

OTL: otolaryngology.