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Use of balloon catheter dilation *vs.* traditional endoscopic sinus surgery in management of light and severe chronic rhinosinusitis of the frontal sinus: a multicenter prospective randomized study

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Abstract. – OBJECTIVE: Chronic rhinosinusitis (CRS) of the frontal sinus is a complex pathological condition and many surgical techniques were described to treat this area endoscopically, like traditional endoscopic sinus surgery (ESS) and balloon catheter dilation (BCD).

PATIENTS AND METHODS: We designed a multicenter prospective randomized study to assess the validity and safety of BCD vs. ESS in symptomatological chronic rhinosinusitis of the frontal sinus enrolling a population of 102 adult patients (64 men and 38 women; overall 148 frontal sinuses studied) with non-polypoid CRS. For a better evaluation of the disease, in our study we decided to analyze both radiological (Lund-McKay CT scoring modified by Zinreich) and symptomatological results (SNOT-20 questionnaire). We divided the population affected in two groups, one with light/mild frontal CRS and the other with moderate/severe frontal CRS, basing on radiological findings at Lund-MacKay modified by Zinreich score. Every group was divided in two subgroups, in one we used BCD and in the other we used traditional ESS.

RESULTS: The current literature does not support the suggestion that indications for BCD and ESS are identical, and additional research is needed to determine the role for BCD in specific patient populations. The results showed a not statistically significative difference between BCD and conventional ESS of the frontal sinus in patients with light/mild CRS and in patients with moderate/severe CRS at Lund-Mackay modified by Zinreich score. The same not statistically significative difference was observed comparing the results of SNOT-20 questionnaire in the group of light/mild frontal chronic rhinosinusitis. However, we noticed a statistically significant better outcome of SNOT-20 score in patients with moderate/severe chronic rhinosinusitis that underwent BCD of frontal sinus compared to ESS.

CONCLUSIONS: BCD and ESS are two alternative weapons in the baggage of every endoscopic surgeon, even because they present similar outcomes, safeness and effectiveness both in light/mild and moderate/severe chronic rhinosinusitis of the frontal sinus. An interesting result of our study was the statistically significant better outcome of SNOT-20 score in patients that underwent BCD of frontal sinus for a moderate/severe CRS, compared to those that underwent a traditional ESS.

Key Words:
Chronic rhinosinusitis, Frontal sinus, Endoscopic sinus surgery, Balloon catheter dilation.

Introduction

Chronic rhinosinusitis (CRS) is a common disease with a prevalence between 5% and 15% of the population and it has a considerable impact on quality of life, schooling, work, and ultimately, health spending[1].

Medical therapy is mainly based on the administration of topical or systemic antinflammatory, corticosteroids and antibiotics, but when it is no longer capable of treating pathology, surgical therapy becomes necessary[2].

CRS of the frontal sinus is a challenging, constantly evolving and extremely controversial con-

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dition and is usually associated with high long-term revision rates (10% to 20% of patients), independently to the approach[2-5]; during the years, many surgical techniques have been described to treat this area endoscopically[6,7] and usually, endoscopic approach may be performed with the preservation of the structure and the function of the sinus through functional endoscopic sinus surgery (ESS or FESS). In effect, it is well known that ESS produces significant and durable improvement in all the subjective measures of nasal airflow and all the sinusitis symptoms[8].

Paranasal sinus balloon catheter dilation (BCD) represents a quite recent possibility of intervention in the management of CRS. BCD is a minimally invasive procedure, which seeks to restore physiological sinus drainage through microfractures, so as to prevent abnormal scarring associated with mucosal stripping[9]. The current literature suggests that can safely dilate the frontal, sphenoid and maxillary sinuses with ostial patency in a large number of cases for up to two years.

Currently, there are four companies with U.S. Food and Drug Administration (FDA)-cleared balloon dilation systems: Acclarent* (Menlo Park, CA, USA), Entellus Medical* (Plymouth, MN, USA), Ventera* (Reston, VA, USA), and Medtronic* (Dublin, Ireland).

The purpose of this study was to evaluate the effectiveness, safety, and correct indication of BCD of the frontal recess in the management of CRS of the frontal sinus *vs.* traditional ESS, trying to establish the role that this surgical technique should play in the management of frontal CRS.

Patients and Methods

We designed a multicenter (Policlinico Umberto I, Rome, Italy; Bassini Hospital, Milan, Italy; Niguarda Hospital, Milan, Italy) prospective randomized study to assess the validity and safety of BCD in symptomatological CRS of the frontal sinus *vs.* traditional endoscopic surgical treatment (ESS).

Following the institutional approval of the protocol and after obtaining an informed consent, a population of 102 adult patients (64 men and 38 women; overall 148 frontal sinuses studied) with non-polypoid CRS (according to the criteria defined by the European Position Paper on Rhinosinusitis and nasal Polyps Group 2012) were enrolled. The patients were recruited from the day hospital of the 3 different facilities; at the time of surgery, the subjects were aged between 17 and 57 years (mean 42 years). All patients were studied prior to surgery by collection of medical history data, followed by otorhinolaryngologic examination, the SNOT-20 subjective symptomatological test[10], the endoscopic examination of nasal cavity and CT in axial, coronal and sagittal planes of paranasal sinuses. The degree of every frontal sinus involvement at CT was evaluated using the Lund-MacKay score system modified by Zinreich[11] (Table I).

For a better evaluation of the disease, in our study we decided to analyze both radiological (modified Lund-McKay CT scoring) and symptomatological results (SNOT-20 questionnaire). We added SNOT-20 to the evaluation because, although CT scoring are objective metrics, it is well known that often they do not correlate well with rhinologic symptoms[12].

All patients had been subjected to medical therapy (antibiotics, corticosteroids and nasal irrigations with saline solution) for at least two months, in accordance with EPOS guidelines, and had not shown improved evaluation criteria. At the end of the cycle of therapy, they were thus considered as "non-responders" and were referred to surgery.

Exclusion criteria of our study were: pregnancy, previous sinus surgery, cystic fibrosis, paranasal sinus tumors, allergy to NSAIDs, coagulopathy, use of anticoagulants, osteoneogenesis or Paget's disease, a previous glaucoma diagnosis, and history of facial trauma with distorted sinus anatomy.

Informed consent was obtained prior to surgery from designated research staff. The Ethical Committee approval was grant by "Sapienza University", (Rome, Italy)

We studied every patient before any surgical treatment with a pre-operative TC and a SNOT-20

Table I. Zinreich staging system.

Right	Left
Maxillary	Maxillary
Anterior ethmoid	Anterior ethmoid
Posterior ethmoid	Posterior ethmoid
Sphenoid	Sphenoid
Frontal	Frontal
Osteomeatal complex	Osteomeatal complex
Total (maximum = 54)	

Zinreich Staging System (Modification of Lund-Mackay). Scores Each Sinus 0-5, OMC 0-2. 0 = 0%, 1 = 1-25%, 2 = 26-50%, 3 = 51-75%, 4 = 76-99%, 5 =100%.

questionnaire, and divided our population in two main groups using the modified Lund-MacKay score system:

- Group "L" (light) included all patients with a light/mild involvement of the frontal sinus (appreciated with a lower score (1-2) of Zinreich classification) (71 patients/115 pathological frontal sinuses);
- Group "S" (severe) included all patients with a moderate/severe involvement of the frontal sinus (appreciated with an higher score (3-4-5) of Zinreich classification) (31 patients/33 pathological frontal sinuses).
- At this point, patients of the "L" group were randomly allocated creating the subgroups:
- AL, in which frontal sinus dilatation with BCD was performed (composed of 50 frontal sinuses);
- BL, in which traditional endoscopic surgery of the frontal recess (ESS) according to the Draf 1 procedure was performed (composed of 65 frontal sinuses).
- The same was realized for patients of the "S" group, creating the subgroups:
- AS, in which frontal sinus dilatation with BCD was performed (composed of 19 frontal sinuses);
- BS, in which traditional surgery of the frontal recess (ESS) according to the Draf 1 procedure was performed (composed of 14 frontal sinuses).

There was homogeneity in primary outcome measures (SNOT-20 and Lund-Mackay) between the groups.

Anyway, with the patient under general anesthesia, ESS was performed for each individual case according to the surgical need of the patient. So, septoplasty and/or partial middle turbinectomy were performed to increase access to the frontal sinus outflow.

Patients who had been assigned to balloon dilation of the frontal sinus (subgroups AL and AS) were treated with a 5x16 mm Relieva* sinus catheter (Acclarent), inflated at 14 atm for 10 s, and positionated following the axilla of the middle turbinate under fluoroscopic control[13,14]. If necessary, serial balloon dilations were performed to ensure that the frontal sinus outflow tract was completely dilated in its entire length. A 30° and 45° endoscope was then used to inspect the frontal recess and confirm successful dilation.

In contrast, patients who had been assigned to conventional frontal sinus drainage surgery (subgroups BL and BS) were treated with a Draf I until the frontal sinus ostium was well visualized with the 30° and 45° endoscope. If needed, the dissection included removal of the superior articulation of the uncinate process, the superior aspect of the ethmoid bulla, and the agger nasi cell, as well as any frontal cells that may have been present (Draf IIa).

In both groups, standard postoperative therapy was administered, which comprised antibiotics and oral steroids, nasal irrigations and topical steroids for 1 month. Nasal aspiration for the removal of secretions and scabs was performed every week, according to need.

A new nasal endoscopy was performed after 1 week, 2 weeks, 1 month, 3 months, 6 and 12 months following surgery by the same surgeon.

Endoscopic assessment was performed using direct visualization with a 30° and 70° endoscope and patency of the frontal sinus ostia was confirmed. A 2 mm outer diameter curved suction was also passed into the frontal sinus ostia to confirm patency.

If there was edema, the 2-mm-diameter suction was not pushed through the edema, but the patency of the frontal sinus ostium was measured. If edema was fully obstructing the ostium, this was recorded as not patent.

So, we define the permeability of the frontal recess as a dichotomous variable (yes/no) before surgery and 12 months after surgery.

12 months after surgery, nasal symptoms were reassessed (SNOT-20), and a new tomographic scan was performed after 1 year to evaluate the disease according to the CT Lund-Mackay stage system modified by Zinreich, specifically applied to the frontal sinus[11]. The main outcome measure was resolution of frontal sinus disease shown on CT scan after 12 months follow-up and improvement of symptoms evaluated with SNOT-20 scale.

Some studies have shown that a new stenosis of the frontal sinus occurs within 12 months[15], so we planned the follow-up at 12 months. Effectively, after that time, the frontal sinus achieves a good reepithelization, with a very low risk of restenosis and thus a great likelihood of permanent results.

Statistical Analysis

Statistical analysis was realized with Statistica 10. Data distribution was tested by Kolmogorov-Smirnov test. Statistical analysis was performed with 2 × 2 ANOVA for repeated measures by comparing baseline and post-treatment values in the two groups of patients. The post-hoc test was done with the SNK test; $p < 0.05$ was con-

sidered statistically significant. The interaction between treatments and time was evaluated to compare the effectiveness of the two treatments in the groups.

Results

Group AL comprised 50 frontal sinuses treated with BCD and presented a preoperative mean SNOT-20 of 60.94 and a mean Lund-MacKay frontal sinus CT preoperative grading modified according to Zinreich of 1.68.

Group BL comprised 65 frontal sinuses treated with traditional surgery and presented a preoperative mean SNOT-20 of 65.54; the mean Lund-MacKay frontal sinus CT preoperative grading modified according to Zinreich was 1.57.

The statistical comparison between the two groups did not show significant differences in terms of SNOT-20 or radiological grading (p-value > 0.05).

Group AS comprised 19 frontal sinuses treated with BCD and presented a preoperative mean SNOT-20 of 64.79 and a mean Lund-MacKay frontal sinus CT preoperative grading modified according to Zinreich of 3.10.

Group BS comprised 14 frontal sinuses treated with traditional surgery and presented a preoperative mean SNOT-20 of 67.28; the mean Lund-MacKay frontal sinus CT preoperative grading modified according to Zinreich was 3.07.

Even here the statistical comparison between the two groups did not show significant differences in terms of SNOT-20 or radiological grading (p-value > 0.05). Postoperative results at 12 months showed interesting results (Table II):

- In subgroup AL (BCD in light sinusitis) the mean SNOT-20 decreased from 60.94 to 24.60 while the mean Lund-Mackay CT score in frontal sinuses decreased from 1.68 to 0.58. No patients were lost at the 12-month follow-up and 47 frontal sinuses out of 50 seemed patent after one year (94%) assessed with endoscopic evaluation.
- In subgroup BL (Draf 1 in light sinusitis) the mean SNOT-20 decreased from 65.54 to 27.54 while the mean Lund-Mackay CT score in frontal sinuses decreased from 1.57 to 0.54. No patients were lost at the 12-month follow-up and 62 frontal sinuses out of 65 seemed patent after one year (95.3 %) assessed with endoscopic evaluation.
- In subgroup AS (BCD in severe sinusitis) the mean SNOT-20 decreased from 64.79 to 23.47 while the mean Lund-Mackay CT score in frontal sinuses decreased from 3.10 to 0.53. No patients were lost as the 12-month follow-up and 18 frontal sinuses out of 19 seemed patent after one year (94.7 %) assessed with endoscopic evaluation.
- In subgroup BS (Draf 1 in severe sinusitis) the mean SNOT-20 decreased from 67.28 to 30.71 while the mean Lund-Mackay CT score in frontal sinuses decreased from 3.07 to 0.78. No patients were lost as the 12-month follow-up and 13 frontal sinuses out of 14 seemed patent after one year (92.85 %) assessed with endoscopic evaluation. The preoperative and postoperative score of Lund-Mackay CT score in AL and AS groups demonstrated a significant reduction ($p < 0.05$), the same happened for BL and BS groups ($p < 0.05$). Comparison between the two tecniques was not significant in light sinusitis ($p = 0.30$) (Figure 1) and severe sinusitis ($p = 0.38$) (Figure 2).

Comparing preoperative and postoperative SNOT-20 score in patients treated with BCD in both light and severe sinusitis (AL-AS) we found that there was a significant reduction ($p < 0.05$). We found the same result in patients treated

Table II. Average and standard deviation.

	Lund-Mackay				SNOT-20			
	Average		Standard deviation		Average		Standard deviation	
Group	Pre	Post	Pre	Post	Pre	Post	Pre	Post
AL	1.68	0.58	0.47	0.61	60.94	24.6	8.43	8.85
AS	3.10	0.53	0.31	0.61	64.79	23.47	7.59	6.32
BL	1.57	0.54	0.50	0.59	65.54	27.54	10.04	7.43
BS	3.07	0.78	0.27	0.80	67.28	30.71	13.31	10.18

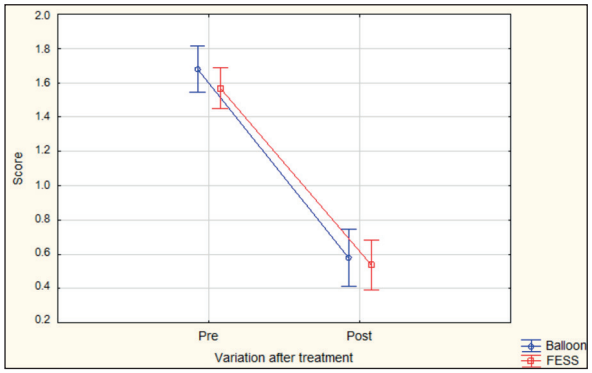

Figure 1. Lund-Mackay CT score Balloon *vs.* Fess light sinusitis.

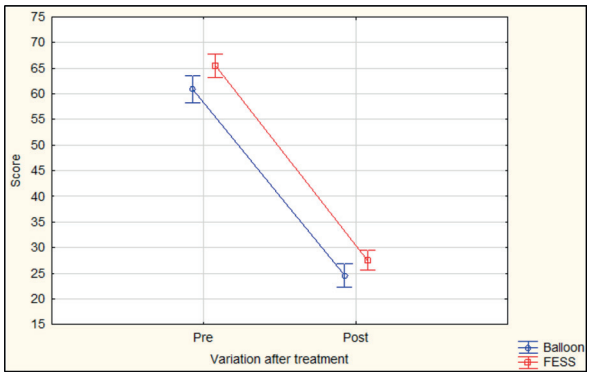

Figure 3. SNOT-20 score Balloon *vs.* Fess light sinusitis.

with ESS (BL-BS) ($p < 0.05$). The comparison between the two tecniques for light sinusitis (AL *vs.* BL) was not significant ($p = 0.42$) (Figure 3). There is statistical significance in SNOT-20 score in the comparison between the two techniques in patients with severe sinusitis (AS *vs.* BL) ($p < 0.05$) (Figure 4).

The patency of the frontal recess also observed in day-hospital endoscopy was thus similar in 4 subgroups and there weren't significative variations.

The 4 cases of frontal recess obstructed following Draf I and the other 4 cases of frontal sinuses obstructed after BCD, were subjected to Draf II surgery, and in 7 cases anatomical and radiological resolution were achieved. We had 1 synechia in group BL, which was solved with endoscopic surgery. No major complications were observed in either group, although minor epistaxis were reported occasionally. None of our patients developed any complication as a result of the BCD procedure including orbital or skull base dehiscence and mucocele formation.

Discussion

CRS of the frontal sinus is a challenging, constantly evolving and extremely controversial condition; CRS may be typically defined as chronic inflammation due to an altered environment-host interaction at the nose/sinus interface. A particular biofilm constitution with a different bacterial location may increase resistance to standard therapies[16]. Failures, thus, depend on the relative difficulty in gaining a therapeutic understanding of the various aspects of CRS pathogenesis, which is definitely multifactorial. Infectious factors (bacterial, including biofilm, viral and fungal), indeed coexist with allergic and inflammatory factors (affecting the mucosa and the underlying bone), and mucociliary clearance deficiency[17,18].

All of these causes determine extreme individual variability, also in the response to medical or surgical treatment[19,20].

Tissue reactivity (mucosal and bony) plays a very important role in exacerbating CRS; so, for the long-term reduction of mucosal inflammation

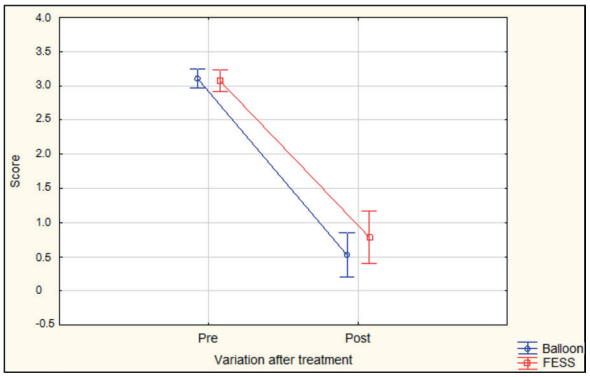

Figure 2. Lund-Mackay CT score Balloon *vs.* Fess severe sinusitis.

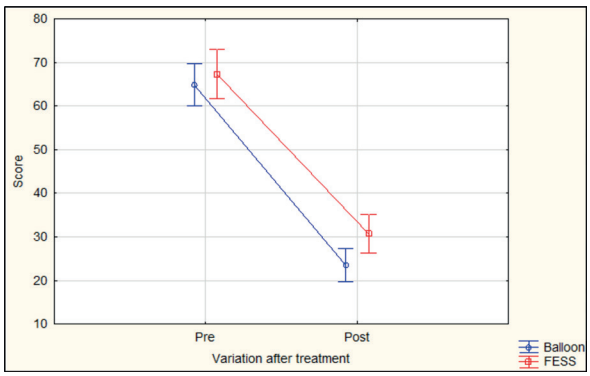

Figure 4. SNOT-20 score Balloon *vs.* Fess severe sinusitis.

this is one of the keys for therapeutic success[21]. In fact, many patients with advanced sinus disease will never demonstrate a change in their clinical and radiological situation because of the nature of their biology and for many of them, there is no surgery or medicine that will normalize their sinus mucosa on imaging.

ESS restores physiological anatomical sinus drainage, opening "the pre-chambers" (Messerklingen)[22] or sinus transition space (Setliff)[23], thus fostering the respect and preservation of normal mucosal clearance. This principle is extremely important especially in the frontal sinus. In this area, the preservation of the mucosa is crucial in order to prevent a new stenosis of the frontal recess and thus, subsequent complex and potentially dangerous revision procedures.

The concept of minimally invasive dilation technology with a balloon was already utilized in several surgical fields[24-27] and the application in paranasal sinus ostia was described in 1993 by Lanza[28] with the approvation of the US Food and Drug Administration in April 2005, with initial safety and feasibility studies reported the following year[13,29].

BCD is essentially a "transition space instrument", targeting at first the ethmoidal infundibulum and the frontal recess (the sphenoid sinus does not have a real transition space and is less involved with inflammatory disease). These "spaces" (for Setliff), or "prechambers" (for Messerklinger) are narrow, with a maximum diameter of 1.5-2 mm, and even less in many symptomatic patients. The positioning of a submillimeter guide-wire and a millimeter balloon catheter into these transition spaces can be difficult, but it represents the less traumatic way to approach this anatomic area. Once in place, the balloon is slowly inflated to 10 atm, performing a gradual separation of the opposing walls of the transition spaces. This forced break of the transition space occurs through micro-fractures of the immediate peripheral bone (i.e. uncinate process), which usually keeps its new position. BCD can be used alone as a unique intervention for one or more sinuses, or in combination with traditional ESS, realizing the so called "hybrid" procedure.

As we said before, it is clear that dilation of sinus ostia or their outflow tracts with BCD may enhance mucosal preservation, decrease local trauma, and restore the patency of the sinuses.

In frontal sinus, the concept behind BCD utilization involves the microfracturing and remodeling of bone in the frontal recess, as well. The combination of this improved bony and mucosal patency, may be enough to restore in an atraumatic way the sinus continued drainage. In addiction, the frontal sinuses that failed to show clinical and radiological improvement remains available to further intervention, be that re-dilation or advanced endoscopic traditional surgery.

BCD of the frontal sinus outflow is a simple, effective and relatively safe procedure, as has been shown in several series[30-39], even in cases of acute frontal sinusitis[40], or in revision cases[41], and can also be performed in the office with local anesthesia requirements[42-44].

In literature, there is a lot of evidence about utility, efficacy and safety of BCD as a potentially useful technique that surgeons can use to treat all cases of CRS (even in frontal sinuses) in addition to traditional endoscopic surgery with multiple indications currently reported, and reviews that conclude that indications are no different from those for performing traditional ESS[14,32-34,45-48]. On the contrary there are some authors that considered BCD as a technique that can be used only in few cases because of the numerous anatomic variations of frontal recess and the not common practice to obtain a sample for histopathological examination during the balloon only procedure[49-51].

A recent review[52] concludes that the current literature does not support the suggestion that indications for BCD and ESS are identical, and additional researches are needed to determine the role for BCD in specific patient populations, including revision surgery and CRS with nasal polyposis.

Proponents of BCD emphasize that this is a less invasive surgical technique in terms of anatomical distortion and mucosal disruption, thereby minimizing the risk of synechiae formation and ostial re-stenosis[53,54].

BCD may be also advantageous in the setting of anatomic variants such as obstructing type III or IV frontal cells that are less accessible to current endoscopic instrumentation[55], or in the management of immunocompromised and critical ill patients with acute rhinosinusitis also for possible dangerous complications[39,56].

A potential drawback of BCD is that the instrumentation is not reusable between patients, and the cost of the disposable instrumentation may increase the total cost of the procedure[54,57,58].

Additionally, patients with extensive mucosal disease, such as polyps, are generally not candidates for the current generation of catheters

because the goal of treatment in such cases is resection of edematous, inflamed mucosa[30,55,59].

Other authors affirmed that in case of patients with severe disease, polyps or fungal debris, mucocele, cystic fibrosis, or facial traumas that distort the sinus anatomy, BCD is controindicated and conventional ESS is necessary[14,60].

Ultimately, there have been few rigorous trials comparing risks and benefits of BCD and ESS, and as a result of this limited evidence the 2012 EPOS guidelines conclude, "overall, the place of these systems in the sinus surgeon's armamentarium remains unclear (Evidence Level IV)"[55,59,60-62].

Current recommendations, therefore, cite the need for additional evidence to clarify the specific indications, correct utilization, and better outcomes of this emerging technology[53,61].

As we can see, the role of BCD is yet unclear, and we need additional studies to further evaluate outcomes about the role of BCD in specific patient populations, such as those with moderate to advanced sinus disease, prior ESS, and nasal polyposis[52].

In our trial, we divided the population affected in two groups, one with light/mild frontal CRS and the other with moderate/severe frontal CRS, basing on radiological findings at Lund-MacKay modified by Zinreich score. Every group was divided in two subgroups, in one we used BCD and in the other we used traditional surgery.

The results showed a not statistically significative difference at one year-control between BCD and conventional ESS of the frontal sinus in patients with light/mild CRS ($p > 0.05$) and in patients with moderate/severe CRS ($p > 0.05$), studied with Lund-Mackay modified by Zinreich score. The same not statistically significative difference was observed comparing the results of SNOT-20 questionnaire at one year-control in the group of light/mild frontal chronic rhinosinusitis ($p > 0.05$). An interesting result come instead from the evaluation of SNOT-20 in patients with moderate/severe chronic rhinosinusitis of the frontal sinus after one year of follow-up; we noticed indeed, a statistically significant better outcome of SNOT-20 score in patients treated with BCD *vs.* those treated with traditional endoscopic sinus surgery ($p < 0.05$).

Furthermore, the rate of patency of frontal ostia at the endoscopical evaluation was statistically similar between the patients treated with balloon and with traditional surgery in both groups (light/mild and moderate/severe CRS) at one-year follow-up ($p > 0.05$). The rate of complicance seemed to be the same between BCD and traditional surgery in light/mild disease and moderate/severe disease ($p > 0.05$) demonstrating the similarity between the two techniques. Moreover, we observed the same rate of surgical failure ($p > 0.05$) between the two procedures and these cases were treated with a more radical surgery.

Conclusions

According to current literature, the role of BCD in sinus surgery is yet unclear. We noticed that specific recommendations and indications of BCD use in more-advanced frontal sinus disease (defined as radiological almost total opacification of the frontal sinus) have not been previously addressed. Analyzing our data, we can say that balloon catheter dilation and traditional endoscopic surgery (Draf 1 in ESS) are two alternative weapons in the baggage of every endoscopic surgeon, even because they present similar outcomes, safeness, and effectiveness both in light/mild and moderate/severe chronic rhinosinusitis of the frontal sinus. An interesting result of our study was the statistically significant better outcome of SNOT-20 score in patients that underwent BCD of frontal sinus for a moderate/severe CRS, compared to those that underwent a traditional endoscopic sinus surgery. Even if this test is completely subjective and is based only on the symptoms reported by the patients, if these results will be confirmed by other studies, it could be possible to find some indications to the use of BCD in specific pathological variety of chronic rhinosinusitis.

Conflict of Interest

The Authors declare that they have no conflict of interests.

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