Comments on:

The feasibility of balloon sinuplasty in patients with chronic rhinosinusitis: the Graz experience

P. Tomazic, H. Stammberger, H. Braun, W. Habermann, C. Schmid, G. Hammer and W. Koele. Rhinology 51: 120-127, 2013.

We regret that we find ourselves commenting on this paper from such an eminent centre for endoscopic sinus surgery.

This paper shows an extraordinarily high failure rate in balloon sinuplasty despite the cases apparently having been pre-selected after consideration of the CT scans. Such poor results are contrary to the published literature showing success rates of up to 98% [1-4]. In our experience of many hundreds of cases, failure is extremely rare and we quote a 1-5% surgical failure rate for the process of informed consent. This includes failure of symptomatic relief not assessed here.

In this paper, 42% of the frontal balloon only procedures were successful, with 15 of 22 insertion failures, 4 dilation "failures" and in 3 patients sinuplasty was not tried. The protocol suggests that "at least 4 cannulation attempts were made for each sinus" but not how soon after 4 attempts the surgeon gave up.

The principle of balloon sinuplasty is that the soft end of the guide wire is introduced and reintroduced towards the ostium with repeated rotation of the wire between each introduction, facilitating the "seeking" of the ostium. It frequently takes multiple cannulation attempts before the guide wire enters the sinus and to stop after "at least" 4 insertions will significantly bias towards the failure of this technique.

Fourteen percent of the frontal sinuses were "not tried". This was equated to failure of the technique. The explanation given was that in these cases "massive pathology" was found, surprisingly not evident preoperatively or on CT. Similar arguments apply to the appalling success rate in the maxillary sinus (47% of this failure rate due to not trying) and in the sphenoid sinuses.

The paper's definition of "failure of dilation" uses entirely subjective criteria applied by the operating surgeon, producing bias. The ability to safely dilate the frontal recess and irrigate the frontal sinus is one of the distinct advantages of balloon sinuplasty.

The authors discuss potential circumferential mucosal trauma of the frontal recess by a balloon ignoring the almost invariable circumferential damage when using conventional FESS instrumentation of this area. The Plaza [1] study demonstrates a higher rate of frontal sinus patency in the balloon group (90% patent at 12 months) than conventional ESS (at 68.2% patent at 12 months) in a randomised controlled study.

A 7 mm dilation may well be too small in cases of maxillary fungal balls but these are a specific contraindication to balloon sinuplasty under the Materials and Methods of this paper. There is always a potential that the middle turbinate will be moved whether during endoscopic sinus surgery or balloon sinuplasty and this is very rarely a clinical issue.

While correct that the lateral recesses of a sphenoid cannot be easily inspected through a natural ostium enlarged to 7 mm. Why would one wish to do this in the absence of significant disease shown on a pre-operative scan, which under the terms of the Materials and Methods of this paper excludes the sinus from balloon sinuplasty? The guide wire for a sphenoid balloon can be positioned through the sphenoid ostium under endoscopic control without transillumination. Once the guide wire is in place it is difficult to imagine that dilatation is not possible.

We commend the authors in abandoning the study in the light of their results but feel that balloon sinuplasty has largely been misrepresented here. Further studies are required using teams able to achieve both insertion of the guide wire and dilatation of the sinuses at a rate which does not lay them open to criticism of being biased against the technique.

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References

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2. Hopkins C, Noon E, Bray D, Roberts D. Balloon Sinuplasty: Our first year. J Laryngol Otol. 2011; 125: 43-52.
3. Catalano, P. Balloon dilation technology: Let the truth be told. Curr Allergy Asthma Rep. 2013; 13: 250-254.
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Reply:

Dear Editors,

Thank you for forwarding Mr. Lowe´s and Mr. De Carpentier´s comments on our paper, which we would like to answer as follows:

We share the authors´ concern over the poor results of the Graz´ balloon sinuplasty feasibility study – albeit for reasons different from theirs.

First of all, the study design was not to evaluate improvement of symptoms but whether or not the following goals could be achieved: insertion of the guide wire into the passage / ostium / sinus in question, and appropriate balloon dilation of those pathways, thus hopefully reducing – or ideally avoiding – the need for "bloody cold steel" surgery in our patients. Secondly, the definition of "appropriate / sufficient dilatation" in this study design had to be a subjective one, like it always is in surgery: is this (diameter) what I wanted to achieve ? The findings were objective, however, when passages could not be entered and / or ostia were created in wrong locations. We would like to stress again, that the vast majority of our patients underwent navigated procedures, so investigators / surgeons usually precisely knew the position of their tools and despite this, the major problem we encountered was insertion of the guide wire, much less dilation itself. For an illustrational video clip, please visit www……

Two of the senior authors were company-trained early on and hold a corresponding certificate; beyond that, many a cadaveric test was performed as was a pre-trial series of 37 patients with CRS, to avoid a „learning curve" biasing the study results. Our team may have been less dexterous than others, but by and large we knew how to manipulate …the soft end of the guide wire…with repeated rotation…facilitating the "seeking" of the ostium. Attempts to enter a passage / an ostium could easily last for several minutes each; a minimum of 4 attempts per passage / sinus would add up to a maximum of 12 attempts for one side (24 for both sides), when frontal, maxillary and sphenoid sinuses were tried. The frustane attempts led to significant more mucosal trauma than anticipated.
In our "real world setup" (copyright: H. Levine "Multicenter Registry of Balloon Catheter Sinusotomy Outcomes for 1,036 Patients) in patients with documented CRS, achievements were not nearly as good as reported elsewhere – which leaves a lot of questions open.
Are the Graz numbers too small ? In the above mentioned Registry Study, 27 physician practices participated with a median of 27 patients, range 10 to 178; in the so-called CLEAR Study, 115 patients were treated across 9 physician practices. So the Graz numbers appear to be well in range.

Was the Graz team not trained / experienced enough ? Possibly, but unlikely so (see above). Was / is there bias in the study´s intentions ? Very unlikely, as the Graz group was amongst the greatest enthusiasts when balloon based technologies came up – the ENTrigue "SerpENT" and "Ventera" technologies and Acclarent "Relieva Scout" systems were partially developed or tested and / or modified in the wet laboratories at Graz – and we still believe in a role for dilating instrument principles in the frontal recess – but in our CRS patient cohort simply could not reduplicate the >95% success rate others have described in literature – a very sobering experience. So the discrepancies remain…

By pure coincidence, the Graz paper on October 23, 2013 has been selected by the F 1000 Otolarynology editorial team (Heads of Faculty: Patrick Bradley and Charles Cummings) for F1000Prime :„ *…it was recommended as being of special significance in its field…*" (http://f1000.com/prime/tour).

The reviewer concludes :
"*The study further supports that the role and indications for BSP in the management of medically refractory CRS are poorly defined. Future studies could target validated outcome measures, address specific sinus disease and incorporate a study design to include a more objective way to measure success and failure of BSP.*"

There is little we could add to this statement.

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