Paranasal Sinus Balloon Catheter Dilation for Treatment of Chronic Rhinosinusitis: A Systematic Review and Meta-analysis

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Abstract

Objective. Paranasal sinus balloon catheter dilation (BCD) represents a commonly used tool in the management of chronic rhinosinusitis (CRS) for which the indications, utilization, and outcomes have not been well established. A systematic review and meta-analysis were undertaken to evaluate change in quality of life and sinus opacification following paranasal sinus BCD in the treatment of CRS.

Data Sources. MEDLINE and EMBASE databases.

Review Methods. Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines were utilized to identify English-language studies reporting patient outcomes following BCD for CRS. Primary outcomes included the impact of BCD on validated measures of quality of life and sinonasal opacification.

Results. Systematic review identified 17 studies for qualitative analysis. Studies generally included cases with limited disease based on radiographic opacification. Five studies contained extractable data for change in 20-Item Sinonasal Outcome Test (SNOT-20) 1 year following BCD, with significant improvement in self-reported quality of life (P = .04). Five studies reported a significant change in paranasal sinus opacification following BCD (P < .001). Two studies directly compared change in SNOT-20 between BCD and endoscopic sinus surgery, without demonstration of significant difference in outcome (P = .07). Subgroup analysis found that change in SNOT-20 score was greater after BCD in the operating room than in the office (P = .004).

Conclusion. Current evidence supporting the role of BCD in CRS remains incomplete. Long-term within-group improvements in quality-of-life and sinus opacification scores are demonstrated among a restricted adult population with CRS. Additional study is needed to further evaluate the role for BCD in specific settings and patient subgroups.

Keywords
balloon dilation, quality of life, chronic rhinosinusitis, endoscopic sinus surgery, sinus surgery, ESS

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Paranasal sinus balloon catheter dilation (BCD) represents a recently adopted intervention in the management of chronic rhinosinusitis (CRS). Minimally invasive balloon dilation technology is utilized in several surgical fields,1-4 with paranasal sinus dilation first described in 1993 by Lanza.5 The application of BCD to paranasal sinus ostia was approved by the US Food and Drug Administration in April 2005, with initial safety and feasibility studies reported the following year.6,7

Multiple indications for paranasal sinus BCD are currently reported, with 1 recent review concluding that indications are no different from those for performing endoscopic sinus surgery (ESS).8 Subsequently, adoption of balloon technology appears broad, with a recent review of several American surgical databases reporting inclusion of BCD in 8% of endoscopic sinus surgeries completed in 2011.9,10 Protocols for BCD have also been adopted for use in an office-based setting under local anesthetic.11-13 Despite this broad utilization, few randomized controlled trials comparing BCD with ESS have been completed, with current evidence limited to grade C recommendations for BCD in paranasal sinus inflammatory disease.14 Current recommendations therefore cite the need for additional evidence to clarify the indications, utilization, and outcomes of this emerging technology.15,16

The objectives of this study were (1) to quantify change in quality of life and sinus opacification following paranasal sinus BCD versus ESS in the treatment of CRS; (2) to...
evaluate BCD in specific patient populations, including those with prior ESS, nasal polyposis, and office-based procedures; and (3) to identify differences in secondary outcome measures of recovery time, postoperative complications, debridements, and revision surgery for patients with CRS undergoing BCD versus ESS.

Materials and Methods

A systematic review with meta-analysis was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement (PRISMA guidelines) to evaluate the outcomes of paranasal sinus BCD versus ESS in patients with CRS. Methods of the analysis and inclusion criteria were specified in advance and documented in the Prospero database with registration number CRD42015015823 (http://www.crd.york.ac.uk/prospero/). The primary outcomes included changes in quality of life and radiographic opacification, as well as secondary outcome measures of recovery time, postoperative complications, debridements, and revision surgery.

Eligibility Criteria

Experimental and cohort studies reporting original data in the evaluation of postoperative outcomes among patients undergoing transnasal paranasal sinus BCD for CRS were included. Trials included adult subjects (≥18 years) with or without nasal polyposis. Only English articles were eligible. Case reports and pilot studies evaluating safety as the primary outcome measure were excluded, as were studies evaluating transantral approaches and ostial dilation techniques not involving a balloon catheter. Hybrid studies (BCD + ESS) were included only if data reporting included subgroups of patients undergoing isolated BCD.

Search Criteria

A comprehensive review of the English-language literature was performed of the MEDLINE and EMBASE databases. Search criteria were designed to identify studies evaluating the use of BCD in the treatment of CRS in articles published between 1996 and December 2014. Search criteria encompassed all occurrences in the title or abstract of the terms “chronic sinusitis” or “chronic rhinosinusitis” or “CRS” plus the term “balloon sinuplasty” or “sinuplasty” or “balloon dilation” or “dilatation.” Unpublished data were excluded.

After searches were completed, duplicate records were discarded, and abstracts of all identified studies were independently reviewed by 2 authors (J.M.L., M.J.M.). Abstracts were screened to identify experimental and cohort studies reporting original outcomes in adult patients (≥18 years) receiving BCD in the treatment of CRS. A full-text review of articles with eligible abstracts was then performed. Included in this review was a manual screening of the reference lists to ensure identification of all relevant articles.

Data Extraction

A standardized data extraction template was used for each study. In the case of several manuscripts reporting the outcomes of a single cohort at multiple durations of follow-up, the data from each time point was extracted as a separate entry. Primary outcomes included the impact of BCD on validated measures of quality of life and sinonasal opacification. Additionally, secondary outcome measures of recovery time, global improvement, postoperative debridements, and complications, when provided, were recorded and included in analysis. For each treatment arm, number of patients, sex, age, and preoperative 20-Item Sinonasal Outcome Test (SNOT-20) and Lund-Mackay scores were recorded when available. Additionally, the proportions of patients with nasal polyps and those undergoing office-based or revision procedures were recorded.

The risk of bias was assessed at the study and outcome levels by examining each study for specific markers of validity—including randomization, concealment of subject allocation, blinding of subjects or investigators, proportion of subjects lost to follow-up, and specification of treatment for each subject. The level of evidence was determined to provide an overall estimate of the strength of study design. Additionally, conflict of interest was evaluated with reporting of corporate funding and financial disclosures.

Statistical Analysis

A narrative synthesis of findings in the systematic review of included studies describes demographic characteristics of the target population, intervention received, and reported outcome measures. RevMan 5.3 (Cochrane Group, London, UK) was utilized for pooling of data and completion of meta-analysis. A random-effects model was used to calculate standardized mean differences for continuous outcome variables; 95% confidence intervals (95% CIs) and 2-sided P values are reported. Heterogeneity among included studies was evaluated with the F statistic, with value ≥50% indicating substantial heterogeneity. Descriptive statistics, where applicable, were calculated with SPSS Statistics 18 (IBM Corp, Armonk, New York). Subgroup analysis of weighted means for office versus operating room BCD and recovery time for BCD versus ESS was performed with a 2-sample independent t test of weighted means.

Results

The search strategy identified a total of 92 articles. Title and abstract review identified 22 that met eligibility criteria. Review of the references of these articles identified an additional 17 articles. Full-text review was then completed of all 39 articles, yielding 17 that met eligibility criteria for systematic review. Data extraction for meta-analysis was possible in 11 of the identified studies (Figure 1).

Manuscripts identified for study inclusion are summarized in Table 1. There was homogeneity in primary outcome measures (SNOT-20 and Lund-Mackay), with varied duration of follow-up. Studies were subsequently pooled for quantitative analysis, with 2 additional subgroups reporting outcomes at early (≤6 months) and late (≥12 months) postoperative time points. Itemized assessment of risk of bias is reported in Table 2. Potential conflicts of interest were
identified in 10 studies included in the systematic review, as reported in Table 3.

Change in quality of life following BCD for treatment of CRS was reported with the SNOT-20. Seven studies reported change in SNOT-20 following BCD, with median follow-up of 12 months ($I^2 = 73\%$). Quantitative analysis identified 454 patients, with a standard mean reduction of 1.52 per item (95% CI: 1.17-1.86; Figure 2).11,20,21,23,25-27,30,33 Five studies reported change in SNOT-20 ≤6 months following BCD ($I^2 = 78\%$). Quantitative analysis identified 350 patients, with a standard mean reduction of 1.45 per item (95% CI: 0.99-1.91; Figure 3).11,20,22,24,25 Similar results were obtained when meta-analysis was repeated with the inclusion of data from the 2 retrospective studies.25,30

Change in quality of life following BCD performed solely in the office versus the operating room was evaluated via subgroup analysis. The change in SNOT-20 score was significantly different between the 2 groups and in favor of the operating room procedures ($P = .004$). Office-based BCD was reported for 263 patients, with a weighted mean change in SNOT-20 of –1.37 (95% CI: –1.40, –1.34). Operating room BCD was reported for 107 patients, with a change in SNOT-20 of –1.51 (95% CI: –1.63, –1.38).

Sinonasal opacification following BCD was reported with the Lund-Mackay score. Five studies reported change in Lund-Mackay score following BCD ($I^2 = 30\%$),11,19,27,29,30,33 which was statistically significant ($P < .001$). Quantitative analysis identified 318 patients with mean baseline LM score of 7.7 and a standard mean reduction of 1.15 following BCD (95% CI: 0.87, 1.43; Figure 5).

Change in SNOT-20 among patients undergoing BCD versus ESS was evaluated in 2 randomized controlled studies ($I^2 = 76\%$).20,24,25 Quantitative analysis identified 110 patients, with a standard mean difference of –0.42 (95% CI: –1.39, 0.55; Figure 6).

Recovery time—defined as the number days to return of regular activity following intervention—was reported in 62 patients undergoing BCD and 54 receiving ESS. Subgroup analysis revealed a shorter recovery time among BCD patients, with a weighted mean of 1.72 days, compared to 4.84 days among the ESS cohort ($P < .001$).

Secondary outcome measures of postoperative complications, debridements, and revision surgery were heterogeneously reported without the consistency or power needed to make statistically valid comparisons. Additionally, subgroup analysis of patients with nasal polyposis or previous ESS was not possible in patients undergoing BCD versus ESS for the treatment of CRS.

Discussion

This meta-analysis demonstrated that BCD for the treatment of CRS in the reported study population has a positive impact on patient quality of life as assessed by a validated measurement. Analysis of 7 studies revealed consistent improvement in SNOT-20 mean item scores (−1.52), as well as at postoperative time points of ≤6 months (−1.45) and ≥1 year (−1.41). These reductions in SNOT-20 item scores exceed the established...
Table 1. Study Data Available for Qualitative Analysis.

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
<th>BCD Cohort, n</th>
<th>SNOT-20</th>
<th>LM</th>
<th>Age, y</th>
<th>Location of BCD</th>
<th>Nasal Polyposis</th>
<th>Revision Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abreu¹⁹ 2014</td>
<td>BCD</td>
<td>13</td>
<td>NR</td>
<td>5.2 ± 2.7</td>
<td>39.9 ± 15.6</td>
<td>OR</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Achar²⁰ 2012</td>
<td>BCD + ESS</td>
<td>12</td>
<td>3.18 ± 0.75</td>
<td>7.92 ± 4.39</td>
<td>38.9 ± 10.9</td>
<td>OR</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Albirton¹¹ 2012b</td>
<td>BCD</td>
<td>37</td>
<td>2.24 ± 0.98</td>
<td>6.38 ± 3.74</td>
<td>54.6 ± 12.5</td>
<td>Office</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Bikhazi²¹ 2014⁴</td>
<td>BCD + ESS</td>
<td>50</td>
<td>2.54 ± 0.92</td>
<td>NR</td>
<td>NR</td>
<td>Office</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Bolger²² 2007⁴</td>
<td>BCD + hybrid</td>
<td>49</td>
<td>2.14 ± 0.97</td>
<td>8.33 (1-21)</td>
<td>47.8 (21-76)</td>
<td>OR</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Brodner²³ 2013</td>
<td>BCD + hybrid</td>
<td>50</td>
<td>1.9 ± 1.1</td>
<td>6.9 ± 4.6</td>
<td>50.8 ± 16.4</td>
<td>OR</td>
<td>N</td>
<td>NR</td>
</tr>
<tr>
<td>Cutler²⁴ 2013⁵</td>
<td>BCD + ESS</td>
<td>50</td>
<td>2.54 ± 0.91</td>
<td>3.2 ± 3.2</td>
<td>47.0 ± 14.6</td>
<td>OR + office</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Friedman²⁵ 2008</td>
<td>BCD + ESS</td>
<td>35</td>
<td>2.8 ± 0.52</td>
<td>NR</td>
<td>43.0 ± 11.7</td>
<td>OR + office</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Gould²⁶ 2014</td>
<td>BCD</td>
<td>75</td>
<td>2.27 ± 0.92</td>
<td>5.0 ± 4.2</td>
<td>50.1 ± 16.7</td>
<td>Office</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Karanfilov²⁷ 2013⁶</td>
<td>BCD</td>
<td>202</td>
<td>2.1 ± 0.90</td>
<td>6.9 ± 3.60</td>
<td>48.6 ± 15.4</td>
<td>Office</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Koskinen²⁸ 2012⁶</td>
<td>BCD + ESS</td>
<td>24</td>
<td>NR</td>
<td>NR</td>
<td>46 ± 23-65</td>
<td>OR</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Kuhn²⁹ 2008⁷</td>
<td>BCD + hybrid</td>
<td>23</td>
<td>2.01</td>
<td>5.96 ± 7.53</td>
<td>NR</td>
<td>OR</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Kutluhan³⁰ 2009</td>
<td>BCD + hybrid</td>
<td>30</td>
<td>1.28 ± 2.54</td>
<td>4.75 ± 9.43</td>
<td>38.3 ± 11.37</td>
<td>OR</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Levine³¹ 2008⁷</td>
<td>BCD + hybrid</td>
<td>328</td>
<td>NR</td>
<td>NR</td>
<td>47.2 (18-92)</td>
<td>OR + office</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Luong³² 2008⁷</td>
<td>BCD</td>
<td>6</td>
<td>NR</td>
<td>NR</td>
<td>55 (36-68)</td>
<td>Office</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Raghunandhan³³ 2013⁵</td>
<td>BCD</td>
<td>20</td>
<td>68.60%</td>
<td>47.70%</td>
<td>NR</td>
<td>OR</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Weiss³⁴ 2008⁷</td>
<td>BCD + hybrid</td>
<td>28</td>
<td>2.07 ± 1.03</td>
<td>5.67 ± 4.58</td>
<td>NR</td>
<td>OR</td>
<td>N</td>
<td>N</td>
</tr>
</tbody>
</table>

Abbreviations: BCD, balloon catheter dilation; ESS, endoscopic sinus surgery; LM, Lund-Mackay; N, no; NR, not reported; OR, operating room; SNOT-20, 20-Item Sinonasal Outcome Test; Y, yes.

Values presented as mean ± SD or mean (range), unless noted otherwise.

ORIOS study
REMODEL study.
CLEAR study.
Not included in quantitative analysis.

Table 2. Itemized Assessment of Risk of Bias for Studies Included in Systematic Review.

<table>
<thead>
<tr>
<th>Study</th>
<th>Direction of Inquiry</th>
<th>Randomization</th>
<th>Blinding</th>
<th>Handling of Lost Data</th>
<th>Basis for Treatment Allocation</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abreu¹⁹ 2014</td>
<td>Prospective</td>
<td>No</td>
<td>No</td>
<td>Excluded</td>
<td>Not given</td>
<td>2b</td>
</tr>
<tr>
<td>Achar²⁰ 2012</td>
<td>Prospective</td>
<td>Yes</td>
<td>No</td>
<td>No dropouts</td>
<td>Random block permutation</td>
<td>1b</td>
</tr>
<tr>
<td>Albirton¹¹ 2012b</td>
<td>Prospective</td>
<td>No</td>
<td>No</td>
<td>Excluded</td>
<td>Patient and surgeon preference</td>
<td>2b</td>
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<tr>
<td>Bikhazi²¹ 2014⁴</td>
<td>Prospective</td>
<td>Yes</td>
<td>Outcomes assessors</td>
<td>Excluded</td>
<td>One-to-one randomization</td>
<td>1b</td>
</tr>
<tr>
<td>Bolger²² 2007⁴</td>
<td>Prospective</td>
<td>No</td>
<td>No</td>
<td>Excluded</td>
<td>Patient preference</td>
<td>2b</td>
</tr>
<tr>
<td>Brodner²³ 2013</td>
<td>Prospective</td>
<td>No</td>
<td>No</td>
<td>Excluded</td>
<td>Surgeon preference</td>
<td>2b</td>
</tr>
<tr>
<td>Cutler²⁴ 2013⁵</td>
<td>Prospective</td>
<td>Yes</td>
<td>Outcomes assessors</td>
<td>Excluded</td>
<td>Random block permutation</td>
<td>1b</td>
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<tr>
<td>Friedman²⁵ 2008</td>
<td>Retrospective</td>
<td>—</td>
<td>—</td>
<td>Excluded</td>
<td>N/A</td>
<td>2b</td>
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<tr>
<td>Gould²⁶ 2014</td>
<td>Prospective</td>
<td>No</td>
<td>No</td>
<td>Excluded</td>
<td>Not given</td>
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<tr>
<td>Karanfilov²⁷ 2013⁶</td>
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<td>—</td>
<td>—</td>
<td>Excluded</td>
<td>N/A</td>
<td>2b</td>
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<tr>
<td>Koskinen³⁰ 2012</td>
<td>Retrospective</td>
<td>—</td>
<td>—</td>
<td>Excluded</td>
<td>Patient preference</td>
<td>2b</td>
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<tr>
<td>Kuhn²⁹ 2008</td>
<td>Prospective</td>
<td>No</td>
<td>No</td>
<td>Excluded</td>
<td>Patient preference</td>
<td>2b</td>
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<tr>
<td>Kutluhan³⁰ 2009</td>
<td>Retrospective</td>
<td>—</td>
<td>—</td>
<td>Not given</td>
<td>N/A</td>
<td>2b</td>
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<tr>
<td>Levine³¹ 2008²⁵</td>
<td>Retrospective</td>
<td>—</td>
<td>—</td>
<td>Not given</td>
<td>N/A</td>
<td>2b</td>
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<tr>
<td>Luong³² 2008³⁶</td>
<td>Retrospective</td>
<td>—</td>
<td>—</td>
<td>No dropouts</td>
<td>N/A</td>
<td>2b</td>
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<tr>
<td>Raghunandhan³³ 2013³⁵</td>
<td>Retrospective</td>
<td>No</td>
<td>No</td>
<td>Not given</td>
<td>Patient preference</td>
<td>2b</td>
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<tr>
<td>Weiss³⁴ 2008³⁷</td>
<td>Prospective</td>
<td>No</td>
<td>No</td>
<td>Excluded</td>
<td>Patient preference</td>
<td>2b</td>
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</table>

Abbreviation: N/A, not applicable.
threshold of 0.8 in absolute value and may therefore be considered clinically significant. Additionally, the magnitude and duration of improvement in quality of life extend beyond the confounding response shift described following ESS. Several groups of studies—including CLEAR, ORIOS, and REMODEL—report outcomes at increasing duration of follow-up for a single group of patients after BCD. While data were not present to directly evaluate change in outcome parameters for individual patients at multiple durations of follow-up, it was possible to include each time point as a separate outcome measure for quantitative analysis.

Table 3. Commercial Conflicts of Interests in Included Studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Industry Sponsor</th>
<th>Study Support</th>
<th>Financial Relationships</th>
<th>Source</th>
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<tr>
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<td>No</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
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<td>Achar20 2012</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Not reported</td>
</tr>
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<td>Albrighton11 2012</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Acclarent Inc</td>
</tr>
<tr>
<td>Bikhazi21 2014</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Entellus Medical Inc</td>
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<tr>
<td>Bolger22 2007</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Acclarent Inc</td>
</tr>
<tr>
<td>Brodnert23 2013</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Entellus Medical Inc</td>
</tr>
<tr>
<td>Cutler24 2013</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Friedman25 2008</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
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<tr>
<td>Gould26 2014</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Entellus Medical Inc</td>
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<td>Karanfilov27 2013</td>
<td>Yes</td>
<td>Yes</td>
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<td>Koskinen28 2012</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>N/A</td>
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<td>Kuhn29 2009</td>
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<td>Kutluhan30 2012</td>
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<td>Unknown</td>
<td>Not reported</td>
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<td>Levine31 2008</td>
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<td>No</td>
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<td>Acclarent Inc</td>
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<td>Luong32 2008</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
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<td>Raghunandhan33 2013</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Not reported</td>
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<tr>
<td>Weiss34 2008</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Acclarent Inc</td>
</tr>
</tbody>
</table>

Abbreviation: N/A, not applicable.

aCommercial funding in support of study.
bAdministrative and logistical support.
cAuthor financial relationships including consulting fees and stock options related to balloon catheter dilation.

Figure 2. Change in 20-Item Sinonasal Outcome Test score following balloon catheter dilation.

Figure 3. Change in 20-Item Sinonasal Outcome Test score ≤6 months following balloon catheter dilation.
greater change was achieved in patients undergoing BCD in the operating room setting. Interpretation of this change in SNOT-20 score is limited since this comparison was not performed within a single study or cohort of patients and does not offer evaluation of these 2 groups in a head-to-head fashion. Additional study is needed to further evaluate clinical outcomes following office-based BCD.

Improvements in sinonasal opacification following BCD are consistent with quality-of-life findings, as pooled analysis of 5 studies reporting change in Lund-Mackay score revealed a decrease of 1.15 (95% CI: 0.87-1.43) following BCD.

A systematic review identified 2 randomized controlled trials evaluating change in SNOT-20 following BCD versus ESS in the treatment of CRS. Data extraction and meta-analysis identified 110 subjects, without a significant difference in quality-of-life improvements following intervention with BCD or ESS. Qualitative subgroup analysis of self-reported postoperative recovery time showed a significant difference among patients undergoing BCD versus ESS. The external validity of these analyses is limited, however, as patients participating in both head-to-head trials have limited disease severity. Neither study included patients with nasal polyposis or posterior ethmoid or sphenoid disease, with average LM scores among patients undergoing BCD of 7.8 and 3.2.

Postoperative quality of life following BCD has not been reported in a representative population with CRS. Exclusion of patients with nasal polyposis, prior sinus surgery, osteoneogenesis, and ciliary dysfunction limits the disease severity of the included population, as further reflected with a mean preoperative LM score of 7.7 among patients in the current meta-analysis. In comparison, a multi-institutional cohort evaluating CRS treatment outcomes recently reported pretreatment LM values of 13.3 (n = 40) and 13.1 (n = 152) among patients respectively undergoing medical and surgical treatment. Additionally, Ashraf et al identified a mean “normal” LM score of 4.26 (95% CI: 3.43-5.10) among patients undergoing computed tomography of the paranasal sinus region for reasons unrelated to sinusitis. This normal value is comparable to the preoperative mean LM score among patients in several studies included in the present analysis. While it has been established that LM score does not correlate with measures of sinonasal quality of life (SNOT-22), the low opacification score combined with exclusion of multiple forms of advanced CRS limits the evaluated population to a select subset of CRS patients with limited disease.
Additional study of patients with advanced CRS is necessary to further support the use of BCD among all patients with CRS.

Exclusion of patients undergoing hybrid procedures (BCD as part of ESS) from systematic review may limit the generalizability of the study findings. Our study design intentionally separated the BCD and ESS groups to minimize confounding variables in analysis; however, this artificial separation may not be clinically necessary. BCD uniquely represents a surgical instrument as well as an operative procedure, and its application may not be limited to single modality interventions.

The high prevalence of industry support introduces a potential conflict of interest in the majority of studies included in this analysis. Quantitative evaluation of studies without industry sponsorship or conflicts of interests was not possible, as only a single study met criteria for meta-analysis when those with possible financial conflicts of interest or industry support were excluded. While the findings of this study are consistent with the above quantitative analysis, future research without industry support is needed to further evaluate this potential bias.

The current literature does not support the suggestion that indications for BCD and ESS are identical. Additional research is needed to determine the role for BCD in specific patient populations, including revision surgery and CRS with nasal polyposis. Further study is also needed to compare the incidence of postoperative complications and debridements among patients with CRS undergoing BCD versus ESS. Finally, additional study is needed to directly evaluate patient outcomes following BCD in the operating room versus office setting.

Conclusion

Current evidence supporting the role of BCD in CRS remains incomplete. Long-term within-group improvements in quality-of-life and sinus opacification scores are demonstrated among a restricted adult population with CRS. Extensive exclusion criteria in the current literature confine evaluation to a subgroup of CRS patients with limited disease. Additionally, the majority of studies are affected by potential conflicts of interest and inherent bias. Additional study is needed to further evaluate outcomes following BCD in the office setting, as well as the role for BCD in specific patient populations, such as those with moderate to advanced sinus disease, prior ESS, and nasal polyposis.

Author Contributions

Joshua M. Levy, study design, data collection, drafting, final approval, accountability for all aspects of the work; Michael J. Marino, data collection, statistical analysis, drafting, final approval, accountability for all aspects of the work; Edward D. McCoul, study design, revision, final approval, accountability for all aspects of the work.

Disclosures

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References


