Association of Amount of Weight Lost After Bariatric Surgery With Intracranial Pressure in Women With Idiopathic Intracranial Hypertension

Mollan, Susan P. MBcHB*; Mitchell, James L. MBcHB*; Yiangou, Andreas MBBS; Ottridge, Ryan S. MPhil; Alimajstorovic, Zerin PhD; Cartwright, David M. PhD; Hickman, Simon J. PhD; Markey, Keira A. PhD; Singhal, Rishi FRCS; Tahrani, Abd A. PhD; Frew, Emma PhD; Brock, Kristian PhD; Sinclair, Alexandra Jean PhD

Effectiveness of Bariatric Surgery vs Community Weight Management Intervention for the Treatment of Idiopathic Intracranial Hypertension
A Randomized Clinical Trial

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74 Patients assessed for eligibility

66 Randomized

33 Randomized to bariatric surgery
  27 Received intervention
    6 Did not receive intervention
      2 Did not attend appointment
      2 Declined surgery
      2 Withdrew from surgery

33 Randomized to community weight management
  31 Received intervention
    2 Did not receive intervention (withdrew consent)

29 Included in intention-to-treat analysis (12 mo)
  4 Not included
    3 Form not available
    1 Declined lumbar puncture

25 Included in intention-to-treat analysis (12 mo)
  6 Not included
    4 Declined lumbar puncture
    2 Forms not available

24 Analyzed in secondary outcome analysis (24 mo)
  9 Not included in analysis
    5 Forms not available
    2 Withdrew consent
    2 Declined lumbar puncture

22 Analyzed in secondary outcome analysis (24 mo)
  11 Not included in analysis
    4 Withdrew consent
    4 Declined lumbar puncture
    2 Lost to follow-up
    1 Form not available

8 Excluded
  5 Did not meet eligibility criteria
  2 Declined participation
  1 Did not attend baseline appointment
<table>
<thead>
<tr>
<th>Outcome or feature</th>
<th>Baseline (Mean SD)</th>
<th>Participants Mean No.</th>
<th>At surgery (Mean SD)</th>
<th>Participants Mean No.</th>
<th>At 2 wk after surgery (Mean SD)</th>
<th>Participants Mean No.</th>
<th>At 12 mo (Mean SD)</th>
<th>Participants Mean No.</th>
<th>At 24 mo (Mean SD)</th>
<th>Participants No.</th>
<th>Difference from baseline to 12 mo Hierarchical regression (Mean SE 95% CI P value)</th>
<th>Difference from baseline to 24 mo Hierarchical regression (Mean SE 95% CI P value)</th>
<th>Difference between arms at 12 mo Hierarchical regression (Mean SE 95% CI P value)</th>
<th>Difference between arms at 24 mo Hierarchical regression (Mean SE 95% CI P value)</th>
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</thead>
<tbody>
<tr>
<td><strong>ICP (intention to treat), cm CSF</strong></td>
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</tr>
<tr>
<td>CWM intervention</td>
<td>34.6 (5.6)</td>
<td>33</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>32.0 (5.2)</td>
<td>25</td>
<td>31.0 (5.7)</td>
<td>18</td>
<td>-2.5 (1.4)</td>
<td>-5.2 to 0.3</td>
<td>.08</td>
<td>-3.5 (1.6)</td>
<td>-6.6 to -0.3</td>
</tr>
<tr>
<td>Bariatric surgery</td>
<td>34.8 (5.8)</td>
<td>33</td>
<td>NA</td>
<td>NA</td>
<td>#</td>
<td>26.9 (8.1)</td>
<td>18</td>
<td>26.4 (8.7)</td>
<td>29</td>
<td>22.8 (7.8)</td>
<td>-8.7 (1.3)</td>
<td>-11.3 to -6.1</td>
<td>&lt;.001</td>
<td>-11.9 (1.5)</td>
</tr>
<tr>
<td><strong>ICP (per protocol), cm CSF</strong></td>
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<tr>
<td>CWM intervention</td>
<td>34.6 (5.9)</td>
<td>33</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>32.4 (6.5)</td>
<td>26</td>
<td>31.4 (5.9)</td>
<td>17</td>
<td>-1.9 (1.4)</td>
<td>-4.6 to 0.7</td>
<td>.15</td>
<td>-3.0 (1.6)</td>
<td>-6.1 to 0.1</td>
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<tr>
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<td>30</td>
<td>NA</td>
<td>NA</td>
<td>#</td>
<td>25.7 (7.5)</td>
<td>28</td>
<td>22.8 (7.4)</td>
<td>23</td>
<td>-9.4 (1.3)</td>
<td>-12.1 to -6.8</td>
<td>&lt;.001</td>
<td>-12.1 (1.4)</td>
<td>-14.9 to -9.3</td>
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<tr>
<td><strong>Weight, kg</strong></td>
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<tr>
<td>CWM intervention</td>
<td>118.5 (20.7)</td>
<td>33</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>116.6 (22.3)</td>
<td>29</td>
<td>116.5 (22.9)</td>
<td>22</td>
<td>-2.1 (2.0)</td>
<td>-6.0 to 1.8</td>
<td>.29</td>
<td>-1.4 (2.2)</td>
<td>-5.6 to 2.9</td>
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<tr>
<td>Bariatric surgery</td>
<td>118.4 (21.8)</td>
<td>33</td>
<td>113.1 (21.7)</td>
<td>27</td>
<td>102.3 (18.8)</td>
<td>18</td>
<td>94.0 (23.7)</td>
<td>30</td>
<td>88.9 (25.9)</td>
<td>24</td>
<td>-23.4 (1.9)</td>
<td>-27.2 to -19.6</td>
<td>&lt;.001</td>
<td>-27.8 (2.1)</td>
</tr>
<tr>
<td><strong>Excess body weight, kg</strong></td>
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<tr>
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<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>49.1 (21.3)</td>
<td>29</td>
<td>49.5 (22.1)</td>
<td>22</td>
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<td>-5.7 to 1.9</td>
<td>.32</td>
<td>-1.3 (2.1)</td>
<td>-5.5 to 2.8</td>
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<tr>
<td>Bariatric surgery</td>
<td>51.5 (20.0)</td>
<td>33</td>
<td>46.2 (20.0)</td>
<td>27</td>
<td>36.5 (16.4)</td>
<td>18</td>
<td>27.2 (22.3)</td>
<td>30</td>
<td>21.2 (24.9)</td>
<td>24</td>
<td>-23.0 (1.9)</td>
<td>-26.8 to -19.3</td>
<td>&lt;.001</td>
<td>-28.0 (2.1)</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
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<tr>
<td>CWM intervention</td>
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<td>33</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>43.1 (7.8)</td>
<td>29</td>
<td>43.5 (8.0)</td>
<td>22</td>
<td>-0.7 (0.7)</td>
<td>-2.1 to 0.7</td>
<td>.35</td>
<td>-0.4 (0.8)</td>
<td>-1.9 to 1.2</td>
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<tr>
<td>Bariatric surgery</td>
<td>44.2 (7.1)</td>
<td>33</td>
<td>42.2 (7.1)</td>
<td>27</td>
<td>38.9 (8.0)</td>
<td>18</td>
<td>35.1 (8.0)</td>
<td>30</td>
<td>32.8 (9.2)</td>
<td>24</td>
<td>-8.5 (0.7)</td>
<td>-9.9 to -7.2</td>
<td>&lt;.001</td>
<td>-10.4 (0.8)</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CSF, cerebrospinal fluid; CWM, community weight management; ICP, intracranial pressure; NA, not applicable. * Intracranial pressure was not assessed until 2 weeks after surgery was performed.
No Significant Difference Between Treatment Arms (12 months), (24 months):

- Headache disability (HIT-6) (p=0.603), (p=0.610)
- Monthly headache days (p=0.247), (p=0.328)
- Monthly analgesic frequency (p=0.257), (p=0.665)
- Headache severity (VRS 0-10) (p=0.231), (p=0.796)
- Pulsatile tinnitus, visual loss, diplopia, TVOs, headache at 12 months

- LogMar visual acuity (p=0.598), (p=0.988)
- Log contrast sensitivity (p=0.411), (p=0.951)
- Perimetric mean deviation (p=0.526), (p=0.863)
- OCT RNFL worst eye (p=0.641), (p=0.695)

<table>
<thead>
<tr>
<th></th>
<th>Baseline n =</th>
<th>12 months n =</th>
<th>24 months n =</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bariatric surgery</td>
<td>32-33</td>
<td>29</td>
<td>28-29</td>
</tr>
<tr>
<td>Community weight loss program</td>
<td>31-32</td>
<td>24-26</td>
<td>22-23</td>
</tr>
</tbody>
</table>
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Figure 1. (A, B) Linear regression analysis plotting change in body weight against change in ICP at 12 and 24 months postbaseline. (C, D) ICP levels of patients categorized according to percentage and absolute weight loss at 12 months since baseline measurements. The dashed red line indicates the idiopathic intracranial hypertension diagnostic threshold of an ICP >25 cm CSF. Data presented as mean +/- SEM. Statistical significance was determined by ordinary 1-way analysis of variance with the Tukey multiple comparisons test. CWI = community weight management intervention; ICP = intracranial pressure.

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Figure 2. Percentage change in diet and surgery groups at baseline, 12-month, and 24-month timepoints for (A) body weight; (B) intracranial pressure; (C) papilledema as measured by OCT volume central thickness; (D) monthly headache days; (E) headache severity; and (F) HIT-6 score; data presented as mean +/- SEM. Statistical significance was determined by hierarchical regression modeling in accordance with per-protocol analysis. ***p<0.001. CWI = community weight management intervention; HIT-6 = headache impact test-6; ICP = intracranial pressure; OCT = optical coherence tomography.