The success of blinding in surgical trials

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Avery K; Savovic J; Metcalfe C; Francis NK; Blazeby JM
Blinding
Aim

To explore a method for testing the success of blinding in a feasibility RCT in surgery
The Bang Blinding Index

Responses:

Arm A
Arm B
Don’t Know

0.3 = 30% more than expected guess correctly

Unblinded
100% correct

Null – fully blinded

? Unblinded
100% incorrect

Bang H; Ni L; Davis CE; Assessment of blinding in clinical trials; Controlled Clinical Trials 2004; 25, 143-156
The Bang Blinding Index

Which sort of pain relief do you think you received?

Epidural  Wound infusion  Don’t know

Why do you think this?

……………………………………………………………………………………
……………………………………………………………………………………
……………………………………………………………………………………
……………………………………………………………………………………

If you answered don’t know;

Please guess which one you think you received

Epidural  Wound infusion

Thank you for your help
Qualitative Interviews

- Blinded Interviewer
- Semi-structured schedule
- Reasons for guess
- Views about blinding
- Reliability of blinding index

Savage Chickens by Doug Savage

IF YOU WERE A TREE, WHAT KIND OF TREE WOULD YOU BE?
I'D BE THE TREE TURNED INTO PAPER FOR PRINTING "THE DUMMIES' GUIDE TO INTERVIEWING"
Methods

• **Responses:**
  Epidural
  Wound infusion
  Don’t Know

• **Endpoints:**
  • Recruitment rate
  • Blinding methods
  • Outcome measures
  • *1º outcome:* patient reported pain

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- Bowel disease requiring laparoscopic surgery
  - Randomisation
    - $N = 34$
  - Epidural
    - $n = 13$
  - Wound Infusion
    - $n = 12$

- Blinding Index day 1
- Blinding Index discharge
## Results - Quantitative

### Original Data

<table>
<thead>
<tr>
<th>Allocation</th>
<th>Epidural</th>
<th>WIC</th>
<th>DK</th>
<th>Total</th>
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</thead>
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<td>5</td>
<td>13</td>
</tr>
<tr>
<td>WIC</td>
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<tr>
<td>Total</td>
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<td>9</td>
<td>8</td>
<td>25</td>
</tr>
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</table>

**Blinding Index**

- **Epidural**: 0.15
- **WIC**: 0.25
- **P**: 0.41

### ‘Forced’ guesses

<table>
<thead>
<tr>
<th>Allocation</th>
<th>Epidural</th>
<th>WIC</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Epidural</td>
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<td>4</td>
<td>13</td>
</tr>
<tr>
<td>WIC</td>
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<td>6</td>
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</tr>
<tr>
<td>Total</td>
<td>14</td>
<td>11</td>
<td>25</td>
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</tbody>
</table>

**Blinding Index**

- **Epidural**: 0.38
- **WIC**: 0
- **P**: 0.43
Results - Qualitative

Wife  I think I know which one you had.
YE19  You do?
Wife  Yes, because your legs were dead.
YE19  Were they?
Wife  Yes. You don’t remember much after the operation.
YE19  No.
Wife  But you couldn’t move your legs. I think you might have had an epidural.

YE22  The reason I thought it was [in my tummy], coz when I had a pain, and then all of a sudden something hit in and took the pain away, and that’s why I thought it was there like.
**Results - qualitative**

**YE20**  
…on a few occasions you’ve asked on one of your sheets to say what I thought I had an because I was getting a bit of numbness in my leg I presumed I was having the epidural. But that doesn’t mean to say it was that.

**YE23**  
I thought it was from my back because I didn’t have any aches and pains in my back, but as for anything else, I don’t know which was which.
Results – Qualitative

CB  Were you happy with the idea of not knowing [which treatment you received]?

YE17  Yes, completely yeah, because then I could guess, coz I could have the thing here and I could guess, you know?

YE18  I was happy with that. Yes, I was happy with that. I, if something like this eventually results in, you know, things being easier for people, I’m all for that. You know, it’s all important.
**Results - Qualitative**

**YE21** They might have thought I would have worried about it. It didn’t worry me.

**YE22** Not really, but erm, I took it from what [the research nurse] was saying and just carried on as she wanted to do it, you know. I was there, for your trial, and that’s how it was.

**YE20** …it was explained to me it was a valid way of doing the trial because you may have a biased view if I knew what pain relief I was getting…
### Results - Comparison

<table>
<thead>
<tr>
<th>YE23</th>
<th>YE17</th>
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</thead>
<tbody>
<tr>
<td>“I thought it was from my back because I didn’t have any aches and</td>
<td>“Because I had a little erm, a little [ball at the side of me here,</td>
</tr>
<tr>
<td>pains in my back, but as for anything else, I don’t know which was</td>
<td>and I felt nothing in my back.”</td>
</tr>
<tr>
<td>which.”</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>From form</th>
<th>From Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain in back, but some in tummy (day 1)</td>
<td>Didn’t feel anything in my back, but had some feeling in tummy (discharge)</td>
</tr>
</tbody>
</table>

Because I felt no pain in my back (discharge)
Summary

Bang Blinding Index

- Simple and reliable
- A simple question is a reliable way to collect data

A test for blinding success is particularly important in surgical trials with a patient reported outcome as the primary endpoint.
Thank you

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