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Informed Decision Making – does research help us?

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By Ann Roberts

Each Christmas, the British Medical Journal offers us a satirical, and often very funny, mock up research study. These are always beautifully written, so that at first glance one almost believes them to be real. This Christmas the study was entitled: "Parachute use to prevent death and major trauma when jumping from aircraft: randomized controlled trial"[1]

As I read it the similarity between this imaginary trial and the 35:39 Induction trial of 2016 was strikingly obvious: "Randomized Trial of Labour Induction in Women 35 Years of Age or Older"[2]

So for those interested in RCTs (randomised controlled trials) and/or induction, but who have neither the time nor patience to read through the detail of either of the above, I have written a short comparison. References to the full trial texts and results are at the end of this article.

The parachute trial, as I will call it, purported to look into the risk of death or major trauma when jumping from an aircraft from a height, either with or without a parachute. Lots of people were invited onto the trial but the majority declined – the risks seemed too high. So the study design had to be altered and the aeroplanes would now be on the ground. Participants joined up to this and were randomised ie put into different groups; with or without parachutes.

The induction trial, as I will call it, was designed to look at how inducing women aged 35 and older at 39 weeks would affect adverse outcomes including Caesarean Birth (CB) rates. Thousands of women were invited to take part over a three year period, but just under 90% declined – the recruitment period had to be extended, and the number of hospitals involved increased to get enough participants to make the trial valid, ending up with 619. They were randomised to induction at 39 weeks or so called Expectant Management (waiting for labour to start spontaneously).

Our local hospital, the Norfolk & Norwich University Hospital (NNUH), invited 143 eligible women, just 10 agreed to enter the trial.

The main outcome of the parachute trial was that there were no deaths or serious injuries whether the participants jumped with or without a parachute - which is a great result.

Conclusions: Parachute use did not reduce death or major traumatic injury when jumping from aircraft in the first randomized evaluation of this intervention. However, the trial was only able toenrol participants on small stationary aircraft on the ground, suggesting cautious extrapolation to high altitude jumps. When beliefs

regarding the effectiveness of an intervention exist in the community, randomized trials might selectivelyenrol individuals with a lower perceived likelihood of benefit, thus diminishing the applicability of the results to clinical practice.

There were also no deaths or serious morbidities in the induction trial, whether the women were induced or not, which is a great result - although by then this was not the primary focus of the trial. The Caesarean Birth (CB) rate was also similar in both groups and this was considered proof that induction does not increase the CB rate.

CONCLUSIONS: Among women of advanced maternal age, induction of labœur at 39 weeks of gestation, as compared with expectant management, had no significant effect on the rate of caesarean section and no adverse short-term effects on maternal or neonatal outcomes.

DISCUSSION

In the induction trial it is a reasonable assumption that the women who agreed to take part were happy to be induced at 39 weeks – perhaps even hoped to be. They may therefore be viewed as a self-selecting group of women who embraced the concept of early induction. Women who did not wish to risk being randomly assigned to early induction declined to enter the trial, just as some people decided not to risk jumping out of an aircraft at altitude without a parachute!

The women were 35 years and older, and they were “primips” i.e. first time mothers, these are both groups who are often told they may have higher rates of intervention and assistance in giving birth. Even so, a CB rate of 32% (induced group) and 33% (waiting group) is high for a group of low risk women. Even higher is the 38% (induced group) and 33% (waiting group) whose babies were assisted out with forceps or ventouse. Only 30% of women in the induction group and only 34% in the expectant management group had a vaginal birth without assistance.

So what happened? Why were these rates of interventions so high?

Looking deeper into the results reveals something that is interesting. As is normal in a RCT, the “intent to treat” principle means that women stay in their groups for the results and analysis, even if they did not conform to the protocol of their group; women cannot be forced into or denied treatment. As a result quite substantial percentages of women in both groups crossed over from one group to another. For example, some women in the induction group went into labour naturally before 39 weeks or declined induction. A surprising number of women in the expectant management group were induced, both for medical and non-medical reasons (e.g. maternal request).

All the women were cared for in consultant led units; we do not know whether the expectant management group were encouraged to labour in a way that maximises straightforward vaginal birth. Epidural use was high in both groups, we know this increases assisted birth rates. Monitoring is not recorded; however, it is likely that most of the women in both groups would have been continuously monitored. We know from numerous studies over the last 40 years that continuous monitoring increases

the caesarean birth rate.[3]

So, just like the parachute RCT – the induction trial took two groups of similar people, who were willing to accept the intervention; treated them in a very similar manner and declared the similarity in outcomes to be proof of something that it really is not.

QUESTIONS

What happened to the women who clearly preferred not to be induced and therefore declined to enter the trial – all 5836 of them? Did they go on to labour spontaneously, did some labour at home or in a MLBU, what were their outcomes? We know that if they avoided induction their likelihood of having a straightforward vaginal birth is considerably higher.[4] We don't know what happened to those women because that's how RCTs work; the more interesting and useful information is not recorded. It would have told us so much more if these women had been followed up.

The media reported the induction trial as if it was a triumph and many in the medical profession seized upon the "no increase in CB following induction" as a go ahead to allow induction rates to rocket, and to recommend early induction to women over 35. *The big question that remains for me is: Why did nobody express any surprise or concern at the extremely high assisted birth rate in both groups in this trial? It is at least double, perhaps three times the average rate in most hospitals.* Many midwives and people who work in the field of birth education have spent many long hours writing their thoughts on this trial – and now I have joined them.[5]

As an antenatal educator with about 12 hours to spend on pregnancy, labour, birth, feeding, baby care and parenting, becoming a family and more, we really haven't time to spend the hours it would take to unpick and challenge RCTs like this one. Luckily, there is some good reading out there, backed by the research that does make sense; I attach some references below. Happy reading and informed decision making – and Good luck!

References:

1. The Parachute Trial: BMJ 2018; 363 doi: doi.org/10.1136/bmj.k5094 (Published 13 December 2018) Cite this as: BMJ 2018;363:k5094
2. The Induction Trial with results: N Engl J Med. 2016 Mar 3;37 4(9):813-22. doi: 10.1056/NEJMoa1509117 www.ncbi.nlm.nih.gov/pubmed/26962902
Full text with all the results here: www.nejm.org/doi/10.1056/NEJMoa1509117?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dwww.ncbi.nlm.nih.gov
3. Continuous Foetal Monitoring in low risk women www.ncbi.nlm.nih.gov/pmc/articles/PMC4010242/
AIMS' information on monitoring in labour: www.aims.org.uk/information/item/monitoring-your-babys-heartbeat-in-labour
4. We know that waiting for labour to start spontaneously and labouring in a low risk environment in the care of midwives can result in lower rates of CB and assisted birth, even for older first time mothers:

www.npeu.ox.ac.uk/birthplace/birthplace-follow-on-study

5. AIMS' Research Review by Gemma McKenzie on the 35/39 trial: www.aims.org.uk/journal/item/induction-and-age

Way back in 2002 midwife Tricia Anderson wrote this article which still resonates today, it is written about midwifery care and home birth but has so much relevance to how we treat women and induction trials in particular: www.pregnancy.com.au/out-of-the-laboratory-back-to-the-darkened-room/