End of the road for the randomized controlled trial in restorative dentistry?

Satisfactory survival of restorations is central to good practice, not only because unfulfilled patient expectations may lead to adverse medicolegal circumstances, but also because third party funders, managers and governments may also be inquisitive as to the performance of clinicians in their pay. However, there seems to be an obsession among researchers with the Randomized Controlled Clinical Trial (RCCT), and, ok, it is the internationally recognized gold standard. The problem is that the RCCT was designed for medicine and the pharmaceutical industry and not specifically for dentistry, where funding is less and the prescription of a drug or treatment is not so often a matter of life or death, as it may be in medicine, surgery or pharmacy. Another problem is that RCCTs are necessarily expensive, given that these should generally continue for a minimum of five years, with sufficient numbers of patients to satisfy a power calculation.

Manufacturers of dental materials and other funders generally appear reluctant to fund RCCTs into the applied performance of dental materials and restorations. Why? Firstly, as mentioned above, they are expensive and the income from the life of a given dental material is not likely to bring in the profits accrued from a lifetime (comparatively higher) sales of a successful new drug being marketed in the pharmaceutical industry. Add to that the difficulties and time in recruiting suitable patients, and then placing the restorations, plus the time spent in actually commissioning and organizing the programme. All of this means, according to Cunningham, that it might be well over six years before a 5-year date is ready for analysis.

Arguably, the most well-known RCCT in restorative dentistry is that comparing the first dedicated posterior composite restorative, Occlusin (developed by ICI when they had a Dental Division), versus amalgam but, by the time they reported the findings at five years, the composite material had changed. It is not a coincidence that ICI Dental was a division of ICI Pharmaceuticals at the time, that being a company with RCCTs of its products ingrained in its psyche. At the time when tooth-coloured materials had become available for placing in posterior teeth, a large three-year study in Liverpool was funded by the Department of Health so that they could establish the acceptability of such products, by way of an RCCT of two amalgams and three composites, with 605 restorations placed at baseline. Despite the results being relatively positive, with no significant difference in the number of failures in the amalgam group and the composite group, the Department of Health did not agree to allow placement of composites in posterior teeth. Two composite materials performed better than the third and there were more mechanical failures in the amalgam group, while failures in the composite group were more likely to be biological in nature.

I have a lot of respect for the Evidence-Based Dentistry supplements which are published with the British Dental Journal from time to time. However, on reading these, one cannot help being struck by the volume of studies which report that there is insufficient RCCT evidence and a need for further well-designed clinical trials. In the most recent issue, of the 15 studies which were summarized, five concluded on a similar theme that:

1. ‘More clinical trials should be performed (topical fluorides in children)’;
2. ‘Due to the small number of RCCTs on this topic and their risk of bias’ (aesthetic preformed crowns);
3. ‘In view of the lack of evidence’ (only one study on bonded vs non-bonded amalgams);
4. ‘No trials met the inclusion criteria – there is a need for well-designed and appropriately conducted clinical trials on this topic’ (best therapies for post-extraction haemorrhage);
5. ‘Insufficient evidence’ (only one study included on BRONJ), ‘insufficient evidence to support or refute use of any particular intervention for management of BMS’.

One cannot underestimate the amount of work which has gone into the original studies and their reviews, so it seems disappointing that more robust conclusions were not always possible. Perhaps the bar was set too high? Not all of the above studies related to restorative dentistry, but the same conclusion may be seen in Cochrane studies on restorative dentistry. Two, in particular, spring to mind. Firstly, the most recent Cochrane...
study on posterior composite, published in 2014.² The reviewers located seven RCCTs, but five were published in or before 1990 (two being the studies referred to above) and the other two, while they were well designed RCCTs, were studies of amalgam vs composite in posterior teeth in 921 children under the age of 12 years – not the real world of general dental practice where the majority of restorations, worldwide, are placed. The authors concluded that amalgam fillings had lower failure rates than composite fillings but, to me, that conclusion could not be justified because the research was on restorations in children. The authors add, rather strangely dismissing their findings, that ‘some materials may no longer be in use or have been replaced by products with better physical properties’. ‘In that case, the results of this review may not be a true reflection on the quality of new restorations currently in use’. A comment which is probably correct, and one is left to ask, should that review ever have seen the light of day? In another Cochrane review of bonded and non-bonded amalgam restorations, only one study met the inclusion criteria and it contained just 31 patients with 113 restorations.¹ I would therefore argue that future Cochrane reviews and, indeed, all future systematic reviews on restoration survival in restorative dentistry, should include well-designed cohort studies which evaluate large numbers of restorations and are of long duration, simply because there are more of these than well-designed RCCTs.

RCCTs, quite correctly, have been described, in a recent, erudite article by Brocklehurst and Hoare,⁶ as ‘the only research design that can demonstrate causality, that is, that an intervention causes a direct change in clinical outcome’. They add ‘there are significant challenges when designing such complex studies, and ‘there is an increasing need for high-quality evidence from primary dental care’. This is all well and good, but who is going to pay? In this regard, a previous analysis, by Hopper and colleagues,⁷ of a failed randomized controlled trial carried out in dental practice, has questioned whether dental practice is the correct arena for carrying out this work. They identified barriers to practitioners participating in RCCTs, including practice disruption, loss of clinical freedom and control, and worries about patient welfare. In other words, will primary care practitioners be happy to place restoration Z when they feel that restoration Y is more appropriate? And, if we cannot get general dentists to be happy carrying out RCCTs when they are working in the real world, is there any point? However, other than for the likes of periodontal mouthwashes and other periodontal interventions, we need to learn – does material X actually provide a decent clinical outcome? A well-designed cohort study can do that.

While I believe that the RCCT is the gold standard for comparing two different interventions, I am not alone in thinking that the RCCT does not work for restorative dentistry. A group of the greats of restorative dentistry, co-ordinated by Reinhart Hickel, have published recommendations for the conduct of controlled clinical studies of restorative dental materials. They stated that ‘there are many publications on clinical studies but, in most cases, it is impossible to analyse and compare results. This is largely due to inadequate design, insufficient reporting on restoration placements, inadmissible pooling of different groups’. As a result, the FDI adopted a new set of ‘standard clinical criteria’ to be applied for the assessment of operative techniques or new restorative materials. These were published simultaneously in three dental journals:¹⁰,¹¹,¹² with the recommendation that these would be useful for quality assessment of restorations placed by general dental practitioners. The criteria were modified in 2010.¹³

So, where does this leave us? The time has come to stop comparing amalgam with resin composite. We already know many of the benefits of using one material over another in general dental practice. The analysis of the NHS payment data has provided good evidence of what works and what doesn’t and it is from the real world of general practice.¹⁴ Surely, analysis of such massive data is the way ahead? But, oops, I forgot, the NHS, in its questionable wisdom, changed the system ten years ago and, now, no-one collects the data and no-one knows whether the public are getting any sort of value for their money. Data are regularly presented on the number of patients seen, the regions where they are seen and that scale and polish is the most frequently delivered treatment,¹⁵ but not on how long-lasting any of the treatments are! A national scandal, when one considers the amount that NHS dentistry costs!

If no massive data are being collected, the key therefore seems to be the development of large practice-based networks, in which practitioners are using a common set of criteria to assess restorations. I repeat that much more information can be gleaned from large ‘real world’ cohort studies from general dental practice, such as that from The Netherlands following two-thirds of a million restorations for nine years,¹⁶ that is an example of how to do it, and the same group have now commenced a large prospective study. Other studies from Denmark, which followed over 4,000 restorations for five years,¹⁷ and one from Brazil, in which the restorations (albeit from one practice!) were reviewed scientifically after 22 years,¹⁸ spring to mind, and there are many more. Perhaps, for restorative dentistry, the Cochrane group should start allowing cohort studies such as these to form the basis of their work. Something needs fixing and we have therefore to consider, for the reasons outlined above, that meaningful data could be obtained if groups of researchers from dental practice could collect data in the same way as they have done successfully in The Netherlands. There would no longer be the need to use outdated or inappropriate studies (as was done for the Cochrane review of posterior composite) because the number of RCCTs was low and the conclusions would be more meaningful than the cry ‘more research is needed’! May the debate begin!

References

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