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[Intervention Protocol]

Rubber dam isolation for restorative treatment in dental patients

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the relative effectiveness and adverse effects of rubber dam isolation compared with other types of isolation used for direct and indirect restorative treatment.

BACKGROUND

Description of the condition

Restorative dental treatments are used to repair damage to teeth caused by caries or trauma. Direct restorative dental treatments (commonly known as 'fillings') repair damage to the visible tooth, such as restorations using either amalgam or a resin composite material. Indirect restorations are prepared outside the patient's mouth, using a dental impression from the prepared tooth. Examples of indirect restorations include inlays, onlays, crowns, bridges and veneers.

Successful restorations depend on a number of factors, but perhaps the most important ones are moisture and microbe control. Excluding moisture and saliva from the tooth or root being restored facilitates the bonding of the restorative material to the tooth and decreases the risk of infection or re-infection. Poor bonding or secondary caries may compromise the success or longevity of the restoration or both.

Description of the intervention

A common method of isolation and moisture control in restorative dentistry is the use of cotton rolls combined with aspiration by saliva ejector. This technique is widely available and low-cost, but has the disadvantage that the dentist is required to replace sodden cotton rolls frequently during the treatment to keep the operative field dry.

An alternative method of isolation of the tooth undergoing restorative treatment is a rubber dam, an isolation method, introduced to the dental profession by Dr Sanford C. Barnum on 15 March 1864 (Elderton 1971a; Elderton 1971b; Elderton 1971c). Since then, many researchers have improved its application and it is now a frequently used, practical alternative to cotton balls (Reuter 1983;

Carrotte 2000; Carrotte 2004; Bhuva 2008). A rubber dam is usually a small sheet of latex (though non-latex versions are available) placed in a frame. A small hole is made in the sheet and placed over the tooth to be treated. The rubber dam is held on to the tooth being restored by means of a small clamp. This isolates the tooth from the rest of the patient's mouth, which keeps the tooth to be restored dry and relatively less exposed to intraoral bacteria. Potential advantages of the use of a rubber dam include superior isolation of the tooth to be treated from the saliva in the mouth (Cochran 1989), providing the dentist with improved visibility, reduced mirror fogging, enhanced visual contrast, soft tissue retraction (Reid 1991), protection of the patient by preventing ingestion or aspiration of instruments, materials, or irrigant (Cohen 1987) and preventing oral soft tissues from contact with irritating or harmful materials used during operative procedures, such as phosphoric acids or sodium hypochlorite (Lynch 2003). There is also a reduction in the risk of cross-infection in the dental practice by decreasing the microbial content of splatters and air turbine aerosols produced during dental treatment (Harrel 2004).

However, there are real and perceived adverse effects to the use of rubber dams. Most often cited are concerns over patient acceptance, time needed for application, cost of materials and equipment, insufficient training, and inconvenience (Koshy 2002; Stewardson 2002; Hill 2008). Latex allergy and damage to the mucosa when placing or removing the rubber dam may also impede the wide use of rubber dam.

A number of recent modifications of rubber dam techniques have been described. John Mamoun suggested the use of a rubber dam with a custom prosthesis to achieve dry-field isolation of the distal molars with short clinical crowns (Mamoun 2002). Also, the slit rubber dam technique used when preparing teeth for indirect restoration could promote operating efficiency (Perrine 2005). Further developments in rubber dam technique are ongoing.

How the intervention might work

Creating a physical barrier around a treatment site to reduce contamination due to moisture and microbes is common practice in medical and dental procedures. Isolating the tooth to be restored from the contamination of moisture or saliva may promote the bonding of the restorative materials to the tooth. The use of a rubber dam in restorative dentistry has the added advantage of providing the dentist with a broader work surface which also traps small pieces of debris and treatment solutions protecting the patient from inadvertently swallowing these. When rubber dams are used in association with amalgam restorations, they may reduce the patient's exposure to potentially harmful adverse effects of mercury ingestion.

Why it is important to do this review

Both rubber dams and cotton rolls are currently used in dentistry to isolate the treatment field and to exclude moisture. There are advantages and disadvantages associated with each method from the different points of view of patient and dentist. Moreover, several randomised controlled trials (RCTs) have been conducted in order to determine whether the use of a rubber dam for restorative treatments influences the treatment outcomes (Raskin 2000; Carvalho 2010; Kemoli 2010). However, the results from these trials appear to be conflicting. The purpose of this systematic review is to evaluate the effectiveness of the rubber dam as an isolation and moisture reduction technique used in restorative dentistry, together with any adverse or negative effects. This information will then be available so that both dentists and their patients can make informed decisions about the benefits and possible negative effects of different isolation and moisture control techniques to be used for specific dental restorations.

OBJECTIVES

To assess the relative effectiveness and adverse effects of rubber dam isolation compared with other types of isolation used for direct and indirect restorative treatment.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials or quasi-randomised controlled trials (including split-mouth/cross-over studies) will be included.

Types of participants

Patients undergoing any type of direct or indirect restorative treatment will be included. There will be no restrictions of age or gender.

Restorative treatment includes direct anterior restorations, direct posterior restorations, inlays, onlays, veneers, crowns, etc.

Types of interventions

The intervention group should receive a rubber dam for isolation and moisture control, either alone or combined with other active treatment (such as saliva aspiration). The comparison (control) group should receive an alternative method of isolation and moisture control (such as cotton rolls) with or without the same active treatment as in the intervention group.

Types of outcome measures

Primary outcomes

1. The survival rate of the restorations at 0.5, 1, 2, 5 and 10 years after restorative treatments. Survival means the restorations were still correctly present or having only a slight wear or defect at the margin less than 0.5 mm in depth when assessed. If the restorations were either completely lost, or were fractured with defects 0.5 mm in depth or greater, had secondary caries or inflammation of the pulp, any of these situations will be labelled as treatment failure.
2. Adverse events. Any reported adverse events related to any of the active interventions during the treatment phase will be noted. These may include events affecting the operator or the patient (e.g. damage to skin or mucosa, allergic reactions to latex).

Secondary outcomes

1. Clinical evaluation of restoration's quality, including colour match, cavo-surface marginal discolouration, anatomic form, marginal adaptation, and caries, which were assessed at baseline (i.e. within 1 month following the placement) as well as 0.5, 1, 2, 5 and 10 years of subsequent recalls. The evaluation should be based upon the US Public Health Service (USPHS) criteria and its evolution (Hickel 2007) which had specific clinical criteria followed for the assessment of each category.
2. Costs: direct cost of treatment, time needed to accomplish the treatment.

Search methods for identification of studies

For the identification of studies included or considered for this review, detailed search strategies will be developed for each database searched. These will be based on the search strategy developed for MEDLINE but revised appropriately for each database to take account of differences in controlled vocabulary and syntax rules. There will be no language restrictions in the searches. Translations of papers will be obtained whenever it is necessary.

Electronic searches

The following databases will be searched:

- Cochrane Oral Health Group Trials Register (whole database, to present issue)
- Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, current issue)
- MEDLINE (via OVID, 1948 to present) (Appendix 1)
- EMBASE (via OVID, 1980 to present)
- LILACs (via BIREME, 1980 to present)
- Scientific Electronic Library Online (SciELO) (1998 to present)
- Chinese BioMedical Literature Database (CBM, in Chinese) (1978 to present)
- VIP (in Chinese, 1989 to present)
- China National Knowledge Infrastructure (CNKI, in Chinese) (1994 to present).

Searching other resources

Searching for unpublished studies and ongoing studies

The following sources will be searched for unpublished and ongoing studies:

- WHO International Clinical Trials Registry Platform (ICTRP, whole database, to present)
- System for Information on Grey Literature in Europe (OpenSIGLE, 1980 to 2005)
- Sciencepaper Online (in Chinese, to present).

Handsearching

Handsearching will also be undertaken, to include:

- *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontology* (1995 to present)
- *Journal of Endodontics* (1975 to present)
- *International Endodontic Journal* (1967 to present)
- *Caries Research* (1967 to present)
- *Journal of Dental Research* (1970 to present)
- *International Journal of Oral Science* (2009 to present)
- *Dental Traumatology* (1985 to present)
- *Australian Endodontic Journal* (1967 to present).

In addition, the results of a programme of handsearching of Chinese dental journals will be explored to identify further included studies.

Reference lists and contacts

The references of the included articles will be screened for studies. Authors and experts in the field will be contacted to identify unpublished randomised controlled trials.

Data collection and analysis

Selection of studies, data extraction and management, and risk of bias assessment will be done by two review authors independently. Any differences of opinion will be resolved by discussion.

Selection of studies

A two-step process will be used to identify studies to be included in this review. Titles and abstracts from the electronic searches will be screened by two review authors to identify studies which may meet the inclusion criteria for this review. Full text copies of all apparently eligible studies will be obtained and these will be further evaluated in detail by two review authors to identify those studies which actually meet all the inclusion criteria. Those studies which do not meet the inclusion criteria will be recorded in the excluded studies section of the review and the reason for exclusion will be noted in the characteristics of excluded studies table.

Data extraction and management

A data extraction form will be designed and pilot-tested on two included studies. The data extraction form will include the following parts.

- Basic information of the article: title, publication time, journal, reviewer ID.
- Inclusion re-evaluation.
- Types of studies: methods of randomisation, methods of allocation concealment, methods of blinding, location of the study, number of centres, time frame, source of funding.
- Types of participants: source of the participants, types of disease, diagnostic criteria, age, sex, eligibility criteria, numbers of patients randomised to each group, number evaluated in each group.
- Types of intervention and comparison: details of the treatments received in the intervention and comparison groups, together with the type of restoration procedure and any co-interventions used.
- Types of outcome measures: name of the outcome, time point that the outcome was recorded, the exact statistics.

All the outcomes will be recorded in Microsoft Access to be well managed.

Assessment of risk of bias in included studies

The risk of bias for each included study will be assessed in each of seven domains using the risk of bias tool as described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). For each domain, explanations will be presented and should be judged as low risk, unclear risk and high risk. The domains and explanations are as follows.

1. Random sequence generation (selection bias): selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.
2. Allocation concealment (selection bias): selection bias (biased allocation to interventions) due to inadequate concealment of the allocation sequence from those involved in the enrolment and assignment of participants.
3. Blinding of participants and personnel (performance bias): performance bias due to knowledge of the allocated interventions by participants and personnel during the study.
4. Blinding of outcome assessment (detection bias): detection bias due to knowledge of the allocated interventions by outcome assessors.
5. Incomplete outcome data (attrition bias): attrition bias due to amount, nature or handling of incomplete outcome data.
6. Selective reporting (reporting bias): reporting bias due to selective outcome reporting.
7. Other bias: bias due to problems not covered elsewhere in the table.

The overall risk of bias of the articles will be judged according to the result of the above seven domains. A study will be judged as at low risk of bias if all the seven domains belong to low risk of bias; and it will be considered as at high risk of bias if at least one domain is classified as high risk; otherwise, it will be considered as at unclear risk of bias.

Measures of treatment effect

For the primary outcome that evaluates the survival/success rate of the restorative treatment, the measure of the treatment effect will be expressed as a hazard ratio. If hazard ratios are not quoted in studies, the log hazard ratios and the standard errors from the available summary statistics or Kaplan-Meier curves will be calculated according to the methods proposed by Parmar et al (Parmar 1998), or the data will be requested from authors. For the primary outcome that evaluates the incidence of adverse events, risk ratio (RR) and 95% confidence intervals (CIs) will be adopted to estimate the treatment effect.

For the secondary outcomes, RR and its 95% CIs will be used for the dichotomous data; and mean difference (MD) and 95% CIs will be adopted for the continuous data.

Other outcomes will be analysed based on the kinds of data that will be retrieved and the measures of treatment effect differs.

Unit of analysis issues

Individuals will be chosen as the unit of analysis. Also, studies with non-standard designs will be considered.

Cross-over/split-mouth trials

Carry-over or carry-across effect of such design will first be assessed if they are considered as a problem. If an ideal study (which reported mean (MD) and standard difference (SD) of both groups and the MD together with SD/standard error (SE) between the two groups) exists, intra-group correlation coefficient (ICC) will be calculated; if more than one ideal study exist, a mean ICC will be calculated. Such ICC will be adopted in the calculation of MD and SD/SE of the other similar cross-over/split-mouth studies. If there is no ideal study, ICC will be assumed as 0.5 (Higgins 2011).

Trials with multiple intervention arms

For those randomised controlled trials with multiple treatment arms, there are two steps to deal with this problem. First, arms will be tried to combine; if it failed, the most relevant treatment groups and controls groups with be chosen to be analysed.
For such trials, the data in all the groups will be collected and recorded in the characteristics of included studies table.

Dealing with missing data

Where information about trial procedures is incomplete or unclear in a trial report, or data are missing or incomplete, review authors will attempt to contact the trial authors to obtain clarification. Where missing data cannot be obtained the trial will not be included in the meta-analysis but results will be described in the text. Where standard deviations are missing from continuous outcome data attempts may be made to calculate these based on other available data (e.g. confidence intervals, standard errors, t values, P values, F values), as discussed in Higgins 2011.

Assessment of heterogeneity

Two kinds of heterogeneity will be considered.

Clinical heterogeneity

The clinical heterogeneity will be judged from the similarity between the types of participants, interventions and outcome measures in each trial.

Statistical heterogeneity

Statistical heterogeneity will be calculated through the Chi^2 test and the measures of effect will be I^2 or P value. The classification of statistical heterogeneity is presented below.

- 0% to 40% implied slight heterogeneity.
- 30% to 60% moderate heterogeneity.
- 50% to 90% substantial heterogeneity.
- 75% to 100% considerable heterogeneity.

Assessment of reporting biases

Reporting bias would be detected by a funnel plot if the number of included studies exceed 10. The asymmetry of the funnel plot will indicate a possibility of reporting bias. Further detection will use Begg's test (Begg 1994) and Egger's test (Egger 1997) for dichotomous data and continuous data respectively.

Data synthesis

Meta-analysis will only be done when there are little clinical heterogeneity and statistical heterogeneity (I^2 < 75%). If the number of studies in one outcome does not exceed four, the fixed-effect model will be used; otherwise, the random-effects model will take the place. Risk ratios will be combined for dichotomous outcomes and mean differences will be used for continuous outcomes measured on the same scales. Where an outcome is measured on different scales, standardized mean differences may be used to combine data from different trials if this is appropriate. And hazard ratios will be combined for the time-to-event data.

Subgroup analysis and investigation of heterogeneity

If there is clinical heterogeneity, subgroup analysis will be implemented, such as subgroup analysis will be done according to the different clinical procedures (restorative treatment and endodontic treatment). If the number of studies in one outcome exceeded 10, meta-regression will be delivered to detect the clinical heterogeneity first and subgroup analysis will be conducted following the results of the meta-regression (meta-regression will be done using STATA 11.0).

Sensitivity analysis

Sensitivity analysis will be done to detect the stability of the outcomes. If there are sufficient included trials sensitivity analysis will be based on risk of bias (low risk of bias versus high or unclear risk of bias).

Presentation of main results

A summary of findings table will be developed for the primary outcomes of this review using GRADEProfiler software. The quality of the body of evidence will be assessed with reference to the overall risk of bias of the included studies, the directness of the evidence, the inconsistency of the results, the precision of the estimates, the risk of publication bias, the magnitude of the effect and whether or not there is evidence of a dose response. The quality of the body of evidence for each of the primary outcomes will be categorised as high, moderate, low or very low (Atkins 2004; Guyatt 2008; Higgins 2011).

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategy for MEDLINE via OVID

1. exp Dental restoration, permanent/
2. exp Dental restoration, temporary/
3. ((dental or tooth or teeth) adj5 (restor$ or fill$)).ti,ab.
4. Dental atraumatic restorative treatment/
5. ((dental or tooth or teeth) and ("atraumatic restorative treatment" or ART)).ti,ab.
6. Dental amalgam/
7. Glass ionomer cements/
8. ((dental or tooth or teeth) adj5 (amalgam$ or resin$ or cement$ or ionomer$ or compomer$ or composite$)).mp.
9. ((dental or tooth or teeth) and (restor$ and (inlay or in-lay or onlay or on-lay or post$ or dowel$ or pin$))).mp.
10. exp Crowns/
11. (dental or tooth or teeth) adj5 (crown$ or coronal$)).ti,ab.
12. or/1-11
13. Rubber dams/
14. ((rubber adj dam$) or (oral adj dam$) or (dental adj dam$) or (latex adj dam$) or Kofferdam).mp.
15. ("Optra Dam" or "OptraDam Plus" or OptiDam or FlexiDam or "Hygenic Fiesta").mp.
16. or/13-15
17. 12 and 16

HISTORY

Protocol first published: Issue 5, 2012

CONTRIBUTIONS OF AUTHORS

- Yan Wang and Chunjie Li proposed the title, registered the review, participated in the writing of the protocol and were first authors of the protocol.
- He Yuan revised the protocol.
- Xuedong Zhou provided advice on the clinical and policy perspective for the review and revised the whole writing.
- Zongdao Shi and May CM Wong provided advice on the methodological perspective for the review, guided and revised the whole writing.

DECLARATIONS OF INTEREST

None known.

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