Adopting minimum intervention in dentistry: Diffusion, bias and the role of scientific evidence

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Abstract

Minimum Intervention (MI) in dentistry aims to empower patients through information, skills, and motivation to take charge of their own oral health and consequently require only minimum intervention from the dental profession. Although MI in dentistry has until now focused mainly on caries-related topics, it follows the 3-step philosophy of disease risk assessment, early disease detection and, if required, minimally invasive treatment. This philosophy is applicable to any type of disease. The subsequent benefit of MI is its focus on disease causes and ultra-conservative, patientfriendly treatment. Successful diffusion of MI depends on substantiation of its beneficial claims through low-bias evidence. Such evidence provides the first step for a wider adoption which, furthermore, depends on complex factors related to adopter behavior.

Introduction

Since the beginning of this millennium information about the procedures and benefits of minimum intervention, an innovative, modern healthcare approach for dentistry, has been increasingly disseminated.[1-8] As with any innovation, wide adoption of minimum intervention by the dental profession is reliant upon factors related to the process of diffusion[9]. This paper aims to contribute to the discussion of this topic by highlighting the role, which both bias and scientific evidence can play in this process.

Minimum intervention

Minimum Intervention (MI) in dentistry aims to empower patients, through information, skills and motivation, to take charge of their own oral health in order to require

only minimum intervention from the dental profession (Hien Ngo, National University of Singapore; oral communication, September 2004). Although the focus of MI in dentistry has so far been on caries-related topics10, the approach follows the 3- step philosophy of disease risk assessment; early disease detection and possible minimally invasive subsequent treatment. Such philosophy is applicable to any type of disease.[2] MI enables the healthcare provider to advise healthy patients about their risks regarding possible future ailments.[11] Such risks may be due to aspects related to a patient's lifestyle or to other factors with the potential to have an impact upon health.[12] These aspects are then assessed to determine the basis on which addressing the identified risk factors with targeted prevention is possible.[13]

Patients with manifest disease are helped by as early as possible identification of such manifestation.[14-16] As disease at an early stage is often relatively contained, treatment can consequently be simple, very conservative and minimally invasive.[1]

Laboratory findings, clinical considerations and protocols, materials and technologies for all three steps of MI in dentistry have been reported elsewhere.[3-6,17] Patients benefit from MI because of its focus on the cause of disease instead of on merely addressing disease symptoms.[7] A further benefit for patients is its patient-friendly nature, due to its minimally invasive treatment options. MI procedures are considered to be atraumatic, since patients experience less discomfort and pain than traditional treatment options incur.[8]

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Table 1
Types of bias in clinical trials

Bias	Description
Selection bias	New clinical procedures are usually tested in clinical trials consisting of 2 groups of patients: One group, forming the control group, is treated with a conventional, most commonly used procedure being considered as "currently accepted standard of care". A second group (test group) is treated with the new procedure. At the end of the study the success (or failure) rates of both procedures are compared. Selection bias occurs when patients are selected into the 2 groups with known or unknown different characteristics. For example, if patients in the test group have conditions, which favor the success of treatment and which are lacking in patients of the control group then the new clinical procedure cannot be credited with the treatment success[43].
Performance bias	Similar to selection bias, performance bias leads to wrong study results if the characteristics of patients in one group of a clinical study support or hinder the treatment effect of a clinical procedure. However, unlike in selection bias, performance bias is induced through active intervention, e.g. through additional treatment during the study in preference to one group only[44].
Detection bias	Detection bias is created if the outcomes of both test- and control group are assessed differently. In other words, if the outcome of one group is assessed more favorably then the other[44].
Attrition bias	Attrition bias occurs when patients allocated to either test- or control group are excluded from the outcomes assessment. For example, if patients in the control group are excluded for whom the standard clinical procedure lead to a treatment success. In such case the overall success rate of the standard treatment would be comparable lower then the new clinical procedure, thus falsely indicating that the later is superior[24].

Experience and expectation of pain and discomfort during dental treatment has been associated with dental fear.[18] A study investigating the dental fear levels of children and adults during atraumatic restorative treatment (ART), in comparison to those receiving traditional restorative treatment using high-speed drilling, found patients treated with ART to be significantly less fearful than the others[19]. Patients with low levels of dental fear are more cooperative during treatment than those with high fear levels[20]. Positive patient attitude and cooperation resulting from reduction of fear during treatment sessions may further benefit the healthcare provider, as a direct correlation between dental fear and operator stress in daily dental practice has been observed.[21]

The MI benefits for patients, attributable to addressing causes of disease and to the reduced discomfort, and the benefits for healthcare providers, resulting from stress reduction through reduced patient fear and consequent higher patient cooperation, have been stated as reasons for adopting MI into daily dental practice.

Table 2
Bias-reducing interventions

Bias	Intervention
Selection bias	(a) Selection of study subjects using a random allocation sequence (b) Concealment of allocation sequence from investigators[24]
Performance bias	Blinding (masking) of study subjects and care providers as to the differences per test- or control group[24]
Detection bias	Blinding (masking) of study assessors as to the differences per test- or control group[24]
Attrition bias	Inclusion of all randomized study subjects into the analysis regardless of their adherence to the study protocol, thus following " intention-to-treat" principle[29,30].

Diffusion of innovation

Despite its stated benefits the still new philosophy of MI faces, as most innovations commonly do, the process of diffusion. Rogers9 (2003) defined "innovation" as an idea, practice or object that is perceived as new, and "diffusion" as the process through which innovation spreads. Diffusion comprises (i) innovation itself; (ii) the type and availability of channels through which the innovation is communicated to others; (iii) time and (iv) the prevailing social system.[9]

The social system constitutes the community of potential adopters of innovation, categorized as follows: the innovators themselves, early adaptors, early majority, late majority and laggards.[9] Rogers (2003) estimated the percentage distribution of these groups as being 2.5%, 3.5%, 34%, 34% and 16%, respectively.[9] Except for the innovators themselves, these adopter groups' responses to innovation can vary between adoption, non-adoption or rejection.[22] An innovation is considered self-sustaining once it has been accepted by 10-20% of all potential adopters.[9] As well as adoption of an effective innovation, rejection and resistance against such an innovation are possible.

Research bias

One of the factors governing the response to an innovation by potential adopters is insecurity concerning uncertainties about the advantages of new ideas, practices or objects as compared to those of current ones.[22] Doubts regarding claims of superiority of, for example, are justified if these are based on studies containing high degrees of bias or systematic error. Bias has been defined as "any process at any stage of inference tending to produce results that differ systematically from the true values".[23] The most important types of bias in clinical studies are selection-, performance-, detection- and attrition bias (Table 1).[24]

Bias may affect studies by causing either an over- or under estimation of the treatment effect of an investigated clinical procedure. This may lead to a situation where a new ineffective treatment procedure is presented as effective or an effective treatment is presented as ineffective. The overestimation of a treatment effect through bias has been observed to be the most common,[25] thus providing the rationale for late

Table 3
Evidence hierarchy

	Study Design
Highest evidence value / lowest bias	Large randomised trials with clear results Small randomised results with unclear results COHORT studies Case-control studies Case series and reports
Lowest evidence value / highest bias	Expert reports

adopters to doubt superiority claims at the onset. Schulz et al. (1995) reported a 41% treatment effect over-estimation due to selection bias alone[26]. Such overestimation would mean that a study comparing the treatment effect of a new clinical procedure against a standard one would report a Risk ratio (RR) of 0.82 while the true RR would only be 1.13. The term "Risk" (R) describes the number of patients having an event (e.g. remaining ill after treatment) (n_{ill}) divided by the total number of patients treated (n_{total}).[27]

$$R = n_{ill} : n_{total}$$

If the effect of treatment with a new procedure is compared with the effect of a conventional, standard procedure, a "Risk ratio" (RR) can be calculated by dividing the patient Risk of remaining ill after treatment with the new procedure (Rnew) by the patient Risk of remaining ill after treatment with the standard procedure (R_{old})[28].

$$RR = R_{new} : R_{old}$$

The so calculated RR indicates whether treatment with the new procedure, in comparison to treatment with the standard procedure, increases or decreases the risk (or chance) that patients may remain ill.[28] A presented RR of 0.82 would imply that the new procedure has reduced the chance of remaining ill for 18% of patients. (A risk ratio of 1.00 would indicate no difference in risk between the two procedures.) However, in a case of a 41% overestimation through bias, a real RR of 1.13 would mean that the new procedure has in fact increased by 13% the chance of patients' remaining ill. If such new clinical procedure were to be adopted into daily practice on the basis of the biased overestimated results, then 13 out of 100 patients treated with the new procedure would have been worse off than they would have been if treated with the standard procedure.

Negative experiences of early adopters of an apparently ineffective innovation, as shown in the example above, would in time lead to its rejection. Early adopters have been described as interacting more frequently with peers than late adopters.[9] Therefore, negative experiences of an innovation by early adopters would be communicated to other adopter groups and this would prevent further diffusion. In that case, the critical mass of 10-20% of adopters[29] would not be reached and the innovation would thus remain unsustainable.

Evidence and diffusion

To avoid negative feedback from early adopters during the diffusion process, an innovation needs to be based on low-bias research because high internal validity of research provides the prerequisite for the successful generalization and adoption of the innovation.[24] Bias reduction in clinical studies focused on treatment is realized through a range of interventions (Table 2) to be considered while planning and conducting a study.[24,29,30]

In addition, it has been acknowledged that various study designs contain various degrees of bias.[31-33] For that reason an 'evidence hierarchy' of study designs has been established (Table 3).[31-33]

It also has been recommended that once a study is conducted, its reporting should follow guidelines in order to assure recognition of study quality.[34] Such guidelines include the CONSORT statement for randomized control trials[35] and the STROBE statement for observational studies, such as Cohort and case-control studies.[36]

Studies with low bias are identified through systematic reviews, using explicit, systematic methods designed to limit bias and the chance effects.[37] Where possible the results of the identified studies are statistically combined, using META analysis and thus providing more precise estimates of healthcare effects.[37]

Despite the value of low-bias evidence, it has been shown that on its own this is not sufficient to facilitate diffusion of innovation.[38]

Nevertheless, diffusion of innovation is more likely if the evidence supporting it is regarded as being strong.[38,39] Furthermore, it has been observed that clinicians do recognize a hierarchy of evidence and most frequently regard randomized control trials (RCT) as the "gold standard".[38] Locock et al. (1999) described RCTs as providing the only form of evidence that may convince clinicians to adopt change.[40] Therefore strong evidence is an important prerequisite for achieving wider adoption of an innovation. Once strong positive evidence regarding an innovation is available, further aspects of diffusion need to be considered. These are related to complex factors of adopter behavior. According to Morris et al. (1989), they may include past educational and professional experiences, work environment and professional and personal aspirations.[41] Fitzgerald et al. (2002) add further considerations related to whether the innovation threatens the established skill base and, consequently, the status and professional position of potential adopters, and to the impact of financial incentives which may facilitate or inhibit adoption of an innovation.[42] The latter may be further reinforced by perceptions of potential adopters as to whether the innovation offers advantages that the current methods do not.[22]

MI Evidence

The need for strong (low-bias) evidence as an important prerequisite for wide adoption of innovation[38-40] applies also to MI. The Cochrane library (online: www.cochrane.org) and Midentistry's compendium database (online: www.midentistry.com/compendium.html) are known sources for evidence generated through systematic reviews and META analyses and cover aspects of disease risk assessment; early disease detection and minimally invasive treatment. The compendium database follows Cochrane recommendations and guidelines regarding the conduct of systematic reviews and META analysis but focuses exclusively on MI topics, including disease treatment and etiology, prognosis and diagnosis.

Conclusions

Minimum intervention (MI) in dentistry focuses on causes of disease and allows for ultraconservative treatment that is more patient-friendly than traditional dentistry. Successful diffusion of MI requires substantiation of its beneficial claims through low-bias evidence. Such evidence provides the first step for a wider adoption, which furthermore depends on complex factors of adopter behavior.

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