Success rate of miniscrew and miniplates as anchorage for orthodontic treatment: A Scoping Review

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ABSTRACT

Introduction:

Conventional anchorage methods generally require patient corporation which may result in undesirable contrary movement of teeth and can be restricted in dentitions that are compromised. Miniscrew and miniplate are specifically designed for enhancing orthodontic anchorage and are being increasingly implemented into orthodontics.

Objectives: **To conduct a scoping review for the evaluation of the success rate of miniscrew and miniplates as anchorage unit during orthodontic treatment.**

Methods: **Strategic and detailed search of the literature in various databases was commenced till October 2020 utilizing free text and MeSH terms, followed by PRISMA to classify different studies for extraction of the data.**

Results and conclusions: **It was concluded that granulation tissue formation and rate of Inflammation was higher in miniplate than miniscrew, however statistical differences were not found. Another factor observed was the effect of mean age on the success rate of miniscrew and miniplate between the age group of 10-20 years and 20-30 years. It was found that the success rate of both miniscrew and miniplate were similar in both the age groups but as the age advanced from 10-20 years to 20-30 years, the success**

rate of miniscrews decreased while it remained constant for miniplates. Based on the length, it was seen that in both primary and secondary insertions 8.0-mm miniscrews were significantly safer than the 6.0-mm miniscrews whereas, for diameter, a screw of 1mm or less was associated with mobility or failure of the miniscrews. In relation to the site of placement in the posterior region miniscrews in the maxilla was a higher success rate than that in the mandible.**Keywords: Miniscrews,Miniplates, Success rate, Maxilla, Mandible.**

MAIN POINTS:

1. Granulation tissue formation and the rate of Inflammation was higher in miniplates than miniscrews.

2. The success rate of both miniscrews and miniplates were similar in both the age groups but as the age advanced from 10-20 years to 20-30 years.

3. The success rate of miniscrews decreased with age from 20-30 years while it remained constant for miniplates.

4. Based on the length, 8.0-mm miniscrews were significantly more stable than the 6.0-mm miniscrews in both primary and secondary insertions

5. Based on diameter, a screw of 1mm or less was associated with mobility or failure of the miniscrews.

I. INTRODUCTION

Anchorage is one of the demandingaspectsof Orthodontics.Headgear, elastics, and a number of other appliances have been suggested as effective forms of orthodontic anchoragefor since long. The use of Conventional anchorage methods generally requires patient cooperation and often results in undesirable tooth movements. Also, their use can be restricted in patients with compromised dentitions.[1]The incorporationof the skeletal anchorage systeminto orthodontic treatment forthe last 25 years has been able to overcome some of these shortcomings of conventional anchorages.

Absolute anchorage needs have paved the way for the developmentof miniscrews and it all started with the use of conventional dental implants, retromolar implants, and palatal implants in fixed appliance therapy. However, different factors like insufficient space, problems in connecting to orthodontic attachments, and cost factor became limiting and this led to the development of smaller devices that could be placed in various locations in the dental arch.[1] Miniscrews and miniplates weredesigned for such purpose and are beingprogressively adopted into orthodontics practice for absolute anchorage needs. The indications for treatment with miniscrew implants include, to name a few, molar protraction, intrusion of supra-erupted teeth, intrusion of posterior in anterior open bite, anterior en-masse retraction, molar uprighting, molar distalization, traction ofimpacted canine, and attachment of protraction facemask.[2]

Recent scientific literatureis replete with articles about the application of miniscrewsin orthodontics and their small size and apparent ease of placement add to their merit. Miniscrews can also be repositioned during treatment to allow all intended tooth movements to be accomplished and they have addedadvantages of low cost, simple surgical placement, and ease of removal. They are small enough to be placed in any space in the alveolar bone, even in interdental areas. However, there are failures as well like fracture at the time of placement, loosening under loading, and impingement on roots either during placement or during tooth movement.

To overcome the limitations of miniscrews, surgical miniplates with intraoral attachments have been used as an

alternateto serve as temporary skeletal anchorage devices (TSAD). Miniplates are associated with less fracture rate than miniscrew and offer the higher advantages of reduced risk of root impingement as they are placed at a safer distance from the roots & also allow the free movement of roots over the TSAD. The initial stability and survival rate of orthodontic mini-implants are highly dependent on the amount of cortical bone at their insertion site. In areas with limited bone availability, miniplates are preferred to provide effective skeletal anchorage.[3]However, the need for surgery and high cost are their disadvantages.

Orthodontic literature has a good number of studies that have evaluated the success of miniscrews based on various parameters which are Granulation formation rate (GFR), Inflammation rate,[4] Mean age & Site of Placement[5] but very few researches have been conducted on the stability of miniplates. However, as per the limited studies available, miniplates are also said to be an equally effective method of enhancing the anchorage but since the number of studies based on the stability of miniscrews exceeds that of miniplates a judicious comparison between the two is not availableso the main aim of this scoping review was to evaluate the success rate of miniscrews and miniplates as anchorage unit for orthodontic treatment based on Granulation formation rate, Inflammation rate, Mean age, and Site of placement.

II. SEARCH STRATEGY AND SELECTION CRITERIA

A scoping review of the literature was conducted to evaluate success rate of miniscrew and miniplates as anchorage for orthodontic treatment. The PRISMA search strategy was planned to use the MeSH terms and Boolean terminology:

((“Success rate”) AND (“Miniscrews”)) AND (“Orthodontics”)/ ((“Success rate”) AND (“Miniplates”)) AND (“Orthodontics”)/ (“Success rate”) OR (“Miniscrews”) AND (“Miniplates”)) AND (“Orthodontics”)/ ((“Success rate”) AND (Miniscrew)) AND (Miniplates)) AND (“Orthodontics”).

This search strategy was applied to the key databases PUBMED, SCOPUS, WEB OF SCIENCE.Furthermore, the reference lists of the included studies and previous reviews were thoroughly searched to identify any potential articles to be included in this review. We restricted searches to trials in human participants with the full text published in English. We also searched Case reports, Grey literature, and unpublished literature in ClinicalTrials.gov, and full research articles were included except abstract for scientific presentation and review papers. The included articles were screened thoroughly, and the level of evidence was determined based on Oxford Centre for Evidence-based Medicine (OCEBM).

INCLUSION CRITERIA:

a) Patients who were treated with orthodontic treatment with the use of miniscrews and miniplates.

- Healthy patients from both genders and from 10 to 30 years of age.
- Optimum Oral Hygiene before treatment with no signs of gingivitis and/or periodontitis.

b) No restrictions on patient’s sex, city, country, ethnicity, and socioeconomic status.

EXCLUSION CRITERIA:

- Patients with poor oral hygiene.
- Those who are not treated with miniscrews and miniplates were excluded.
- Studies done on Animals were also excluded.

III.STUDY DESIGN

- Included those studies in which the investigators used miniscrews and miniplates as anchorage for intervention.
- No restrictions were implemented regarding the follow-up time or the number of participants.
- Studies on the human population published in the English language were included.
- Systematic reviews, Meta-analysis, Randomized Controlled Trials, Case-Control, Cohort studies, Case reports, full research articles, and review papers were included except for the commentaries.

IV.INFORMATION SOURCES

The search was conducted by using the following databases

- PubMed / Medline
- Scopus
- Web of Science

V.LITERATURE SEARCHAND SCREENING

The PRISMA search strategy was planned to use the MeSH terms and Boolean terminology:

((“Success rate”) AND (“Miniscrews”)) AND (“Orthodontics”)/ ((“Success rate”) AND (“Miniplates”)) AND (“Orthodontics”)/ (“Success rate”) OR (“Miniscrews”) AND (“Miniplates”)) AND (“Orthodontics”)/ ((“Success rate”) AND (Miniscrew)) AND (Miniplates)) AND (“Orthodontics”).

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The included articles were screened thoroughly, and the level of evidence was determined based on Oxford Centre for Evidence-based Medicine (OCEBM). (Table.1)

VI.RESULTS

A.1 STUDY SELECTION:

There were a total of 1027 articles identified through the search strategy and sources listed previously. After removal of duplication 941 articles were taken. All the titles were screened, out of which a total of 855 articles were rejected as they were not matching the search question. On the screening of abstracts, 27 articles were excluded as they were not related to success rate, animal

study, or not in the English language. The remaining 59 articles were read for a complete evaluation of the text out of which 31 articles were excluded as they were not meeting the inclusion criteria. Finally, 28 articles were selected for inclusion in this review for qualitative and quantitative synthesis. (Figure 1)

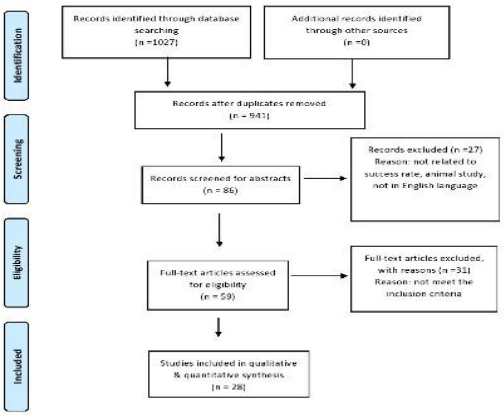

Figure 1. PRISMA Search Algorithm

A.2 STUDY CHARACTERISTICS:

All Included articles were all in English Language and published between 2000 to 2020. The articles included were on subjects treated with miniscrews and miniplates as anchorage for orthodontic treatment. There wasa total of 28 prospective and retrospective studies taken in this scoping review. (Table 2-6)

VII. DISCUSSION

The aim of this scoping review was to evaluate the success rate of miniplates and miniscrews, as skeletal anchorage. These are the most effective bone anchor system method which is used in cases having inadequate dental anchorage required for optimum orthodontic tooth movement. It is well known that articles of prospective and retrospective study both can provide clinical evidence and form the source of a good quality scoping review. Amongst them, there were few articles that compared different factors between miniscrews and miniplates, based on the choice of the clinician and many other factors in choosing the type of anchorage method to be used.

Recent methods such as miniscrewhave proved to be an alternative anchorage system. Through insertion, they are easily placed and removed and can be packed immediately. However, stability is limited after loading with torsion. Miniplates provide various advantages such as high anchorage, less root injury, high success rates, and less risk of fracture.

The aim of this scoping review is to discuss the success rate of miniscrew and miniplates in orthodontics patients. The selected studies are of different level of evidence which was used to answer the clinical question posed in this scoping review. This study included a review of factors (Granulation formation rate, Inflammation rate, Mean age & Site of Placement) related to the success rate of miniscrews and miniplates installed in the maxilla and mandible in different regions.

Among Selected articles there was only one manuscript whichcompared miniscrew and miniplates in terms of granulation tissue formation rate and inflammation rate factors was considered for miniscrew and miniplates. In this study 0.9% of subjects showed granulation tissue formation while using miniplates, whereas only 0.6% showed granulation tissue when palatal screws were used and none of the subjects showed granulation tissue formation in the group where self drilling screws were placed. Similarly, the rate of Inflammation was 7.6% in the

miniplate group which was higher than 1.3% in the self drillingminiscrew group and 2.5% in the palatal screw group.

To study the effect of mean age as a significant factor in assessing the success rate of miniscrews and miniplates, the present study was segregated amongst two mean age groups, ranging from 10 to 20 years for early adolescents and 20 to 30 years for adults.

According to various studies focusing on 10-20 year age group, the overall success rate of miniscrew ranged from 77%-100%.[20,21,23] However when miniplates were used for a similar age group, studies have shown a lesser variation with a mean survival rate of 93.6%.[16,29]

Total of 19 articles for miniscrew and 7 articles for miniplates were selected for evaluating the effect of overall success rate on mean age between 20 to 30 years.

As for the success of miniscrew, Hoi- Jeong Lim et al[12] in their study found that the overall success rate of miniscrews was 83.6% whereas the mandible had a more success rate of 0.48 times than that of the maxilla, similar results were found by Watanabe et al[19] where in a significantly higher success rate was observed in the maxilla(90.6%) when compared to the mandible(70.69%). The possible reason for this has been explained by Kuroda et al[10] who concluded that the proximity of the miniscrew to the root surface is a potential threat for the failure of miniscrew anchorage and this is more evident in the mandible and thus the miniscrew failure rate is more in the mandible than that of the maxilla.

The stability of miniscrew is also dependent on its length, this has been stated by Maino et al.[17] In another study by Suzuk et al,[22] the authors took length as a prime factor to check the stability of miniscrew and found a significantly lower success rate with 5-mm miniscrews in comparison to the 6-mm and 7-mm miniscrews, showing a direct correlation between the length of miniscrew and its stability. In a similar study,Uesugi et al[25] found 8.0-mm miniscrews to be significantly more stable than the 6.0-mm miniscrews. Thus, it can be concluded that a screw with a greater length tends to be more stable than a screw with smaller length.

Another factor that affects the stability of miniscrew is its diameter. G.Janson et al[21] in this study found that a screw with a diameter of 1.0 mm or less was associated with the mobility or failure of the miniscrew. However other authors such as Maino et al[17] have stated that the screw diameter resulted in no significant effects and rather the quality of bone has a greater role to play in the stability of miniscrew where soft bone quality and hard bone quality are threat factors for miniscrew failure, while the superlative results were seen when the screws are loaded into the bone of medium quality i.e. 10-15 Ncm. This has been more elaborately studied by Ichinohe et al[27] who concluded that mini-screws could be stabilized when the cortical bone thickness was ≥1.5 mm. The success rate was significantly higher in groups in which insertion depths of ≥4.5 mm. These results showed that sufficient cortical bone thickness is important for the primary stability of mini-screws with less impact on the screw diameter.

Takashi Watanabe et al[26] conducted a study and concluded that the overall success rate of miniscrew was85.80%. In their study, one of the main factors analyzed was Mean insertion torque where the values were 10.7±1.9 N.cm in the failure group and 8.5±2.1 N.cm in the success group showing that one of the main causes of failure of Miniscrew is increased torque during insertion. Makoto Suzuk[22] also obtained similar results in his investigation in which the miniscrews when it is placed with insertion torque greater than 10Ncm had a lower success rate. This can be a possible explanation for a higher rate of miniscrew failure in the posterior part of the mandible due to the compact nature of bone in that region which tends to increase the insertion torque and leads to poor stability of miniscrew.

One reason which can affect the stability of miniscrew as stated by Hoi- Jeong Lim et al[15] is the clinician's experience. They examined more than 20 miniscrews were placed by more experienced clinicians. The results have shown that there is an approximately 3.6-fold higher success rate of initial stability compared with those placed by less experienced clinicians after adjusting for the insertion site. Thus the results suggested that the initial stability depends on both, the clinician's experience as well as the insertion site.

A similar factor of less clinical importance has been studied extensively by Nikolaos Topouzelis et al[18], who stated that factors such as the number of miniscrews used per patientand correlated with the success rate of miniscrews. It wasnoticed that thesuccess rate decreased by 67% whenever supplementary miniscrew was used in the patient's oral cavity, They also evaluated the soft tissue type of placement resulted in a lower success rate whenever miniscrews were placed in movable mucosa.

With respect to the miniscrews placed on the palatal aspect,Young Ho Kim et al[13] observed that the total number of miniscrews placed for midpalatal resulted inan overall success rate was 90.80%. However,Ramzi Haddad et al[30] concluded that the distance to the alveolar crest was strongly associated with the long-term stability and success of orthodontic mini implants. More apical placement of the miniscrew from the crest is more compstible with a denser and thicker bucco-lingual/palatal bone level and this also enhances the long term stability of miniscrew.

7 articles were selected in which miniplates were used by different authors for mean subject age between 20 to 30 years.

Contrary to the literature available for miniscrews, very few researches have been conducted on the stability of miniplates. However, as per the limited studies available miniplates are also said to be an equally effective method of enhancing anchorage. Of various parameters that were used to evaluate the stability of miniscrews, Shouichi Miyawaki et al[6] concluded that there was no significant association between the success rate and variables such as screw length, location of implantation, surgical approach,loading (immediate or delayed),age or gender and the overall success rate was found to be 96.40% of the studied samples. Similar results were seen in the study conducted by Chung-Ho et al[8] who also confirmed that there was no significant differences in the risk factors for failure of miniplates withan overall success rate of 95.5%.

Although miniplates have proven to be very stable, there are a few demerits that have been reported in a study conducted by Marie A. Cornelis,[1] who observed that the most common problems were postsurgical swellingwhich usually lasts 5 days on average, and also observed thatmore than a third of the patients experienced having cheek irritation initially but it lessened over time and resulted in82% of the patients determines that the surgical experience was better.

Raymond Lam et al[24] also found soft tissue inflammation as the most common complication, which was amenable to focused oral hygiene and antiseptic rinses and also 40% of cases experienced mild complications.

Site of Placement: The placement site of miniscrews in the mandible has shown a significant difference in adults. Cheol-Hyun Moon[5] concluded that dislodgement of the Orthodontic miniscrew implant occurred in the first two months after insertion, when placed in the posterior region of the maxilla & mandible and more than 90% of the failures occurred within the first 4 months. In another study,Makoto Suzuki et al[22] concluded that the success rate of the miniscrews in the maxilla (93.4%) was higher as compared to that in the mandible (70.3%) when miniscrew was placed b/w maxillary second pre-molars and first molars in both maxilla &mandible.AlthoughShouichi Miyawaki et al[6] evaluated the placement of miniplates and concluded that a significant association could not be detected between the success rate and the site of implantation.

The limitation of this scoping review was that various comparative studies which were ideally required were not available which could have helped us in assessing various factors such as bone density, infection, smoking, and gender. Along with this maximum number of studies included were of Level 4 according to the level of evidence as Randomized Controlled Trials and systematic reviews were not available in the literature, and since studies of different levels of evidence were taken for this review a number of other limitations were also found such as small sample size for males as compared to females, subjects who have dropped out of the study during treatment, along with this comparisonwas not done in some studies which might have led us to a certain degree of bias in the present study.

VIII. SUMMARY AND CONCLUSION

For the purpose of orthodontic anchorage, miniscrews, and miniplatesare being progressively adopted into orthodontic practice. However, there are associated factors that cause the failure of miniscrews, like fracture during placement, loosening over time, underloading, and impingement on roots either during placement or tooth movement. On the other hand, miniplates, which are placed at a safe distance from the roots offer the advantages of reduced risk of root impingement and allow free movement of roots past the temporary skeletal anchorage device. Hence, this study was conducted to evaluate the success rate of miniscrews and miniplates during orthodontic treatment.

It was concluded from this scoping review that granulation tissue formation and the rate of Inflammation was higher in miniplates than in miniscrews, however, statistical differences were not found. Another factor that was observed was the effect of mean age on the success rate of

miniscrews and miniplates between the 10-20 years age group and 20-30 years age group. It was found that the success rate of both miniscrews and miniplates were similar in both the age groups but as the age advanced from 10-20 years to 20-30 years, the success rate of miniscrews decreased while it remained constant for miniplates. Based on the length, 8.0-mm miniscrews were significantly more stable than the 6.0-mm miniscrews in both primary and secondary insertions whereas for diameter, a screw of 1mm or less was associated with mobility or failure of the miniscrews. In relation to the site of placement in the posterior region success rate of the miniscrews in the maxilla was higher than that in the mandible.

Table 2. EVALUATION OF RATE OF GRANULATION TISSUE FORMATION &INFLAMMATION RATE ON SUCCESS RATE OF MINISCREWS & MINIPLATES

S.NO	FACTORS	RESULT	OVERALL SUCCESS RATE
1	Granulation tissue formation rate	For Miniscrew- 0% For Miniplate- 0.9%	94%[4]
2	Inflammation Rate	For Miniscrew- 1.3% For Miniplate- 7.6%	94%[4]

Table 3. EVALUATION OF MEAN AGE (FROM 10 TO 20 YEARS) ON SUCCESS RATE OF MINISCREW AND MINIPLATES

S.NO	MEAN AGE FROM 10 TO 20 YEARS	MINISCREWS	MINIPLATES
1	MEAN AGE- 11.4 years	-----	Overall success- 93.6%[29]
2	MEAN AGE - 14.7 years	-----	Overall success- 100%[16]
3	MEAN AGE- 16.99 year	Overall success- 90%[21]	-----
4	MEAN AGE - 18.9 years	Maxilla-100%, Mandible-77.8%[20]	-----
5	MEAN AGE- 19.26 years	Maxilla-93.53%, Mandible-78.31%[23]	-----

Table 4. EVALUATION OF SUCCESS RATE IN MEAN AGE (FROM 20 TO 30 YEAR) FOR MINISCREWS AND MINIPLATES AS ANCHORAGE UNIT.

S.NO	MEAN AGE FROM 20 TO 30	MINISCREWS OVERALL SUCCESS RATE	MINIPLATES OVERALL SUCCESS RATE
1	MEAN AGE- 20.9 years	Maxilla- 93.4%, mandible- 70.3%[22]	-----
2	MEAN AGE- 21 years	maxilla- 90.6%, mandible - 70.69%[19]	-----
3	MEAN AGE- 21.4years	Overall success- 64%[11]	-----
4	MEAN AGE- 21.8 years	Overall success- 84.4 %[6]	-----
5	MEAN AGE- 21.8 years	-----	Overall success- 96.40%[6]
6	MEAN AGE- 21.8 years	-----	Overall success- 86.8%[9]
7	MEAN AGE- 21.8years	Overall success- 84.85%[9]	-----
8	MEAN AGE- 21.9years	maxilla-86%, mandible-76.1 %[12]	-----
9	MEAN AGE- 22.5years	Maxilla-89.7%, Mandible- 68.3%[10]	-----
10	MEAN AGE- 23 years	maxilla- 93.1%, mandible- 93.2%[15]	-----
11	MEAN AGE- 23.2years	Overall success- 81%[14]	-----
12	MEAN AGE- 23.4 years	Male-71.2%, Female-72.2%[27]	-----
13	MEAN AGE- 23.4 years	Overall success- 88.1%[30]	-----
14	MEAN AGE- 23.4years	Overall success- 90.8%[13]	-----
15	MEAN AGE- 23.7 years	-----	Overall success- 92.5%[1]
16	MEAN AGE- 24.6 years	Overall success- 91.4%[17]	-----
17	MEAN AGE- 25.4 years	Overall success- 85.8%[26]	-----
18	MEAN AGE- 25.7 years	-----	Overall success- 94%[4]
19	MEAN AGE- 25.7years	Overall success- 94%[4]	-----
20	MEAN AGE- 27.2 years	Overall success- 90.2%[18]	
21	MEAN AGE- 27.5 years	-----	Overall success- 95.5%[8]
22	MEAN AGE- 27.9 years	Primary: MB-79.1% MP-84.5%[28] Secondary: MB-58.1% MP- 88.9%[28]	-----
23	MEAN AGE- 28.1 years	Primary-80.4%, Secondary-44.2%[25]	-----
24	MEAN AGE- 29 years	Overall success- 89%[7]	-----
25	MEAN AGE- 29 years	-----	Overall success- 89%[7]
26	MEAN AGE- 29.4 years	-----	Overall success- 98.6%[24]

Table 5. COMPARISON OF SUCCESS RATE ACCORDING TO SITE OF PLACEMENT BETWEEN MINISCREWS AND MINIPLATES

S.NO	SITE OF PLACEMENT	MINISCREWS OVERALL SUCCESS RATE	MINIPLATES OVERALL SUCCESS RATE
1	Posterior region of maxilla & mandible	Maxilla- 83.5%, Mandible- 84.1%[5]	------
2	Maxilla & Mandible- B/W maxillary second pre-molars & first molars	Maxilla- 93.4%, Mandible- 70.3%[22]	------
3	Posterior region of maxilla & mandible	------	Posterior Region Upper - 84.1% Posterior Region Lower- 81.6%[6]

TABLE.6 RESULTS OF THE REVIEWED ARTICLES

S.NO	FACTORS	RESULTS SIGNIFICANT TO THE RESEARCH QUESTION
1.	Granulation tissue formation rate and Inflammation rate	More in miniplates as compared to miniscrews[4]
2.	Mean Age (from 10-20 years)	Overall success rate similar in miniscrews and miniplates[16,20,21,23,29]
3.	Mean age (from 20-30 years)	Overall success rate decreased in miniscrews[22,19,11,6,9,12,10,15,14,27,30,13,17,26,18,4,28,15,7] Similar overall success rate in miniplates[6,9,14,8,7,24] there is no statistical difference was found between miniscrews and miniplates.
4.	Site of placement	Posterior region overall success rate of the miniscrews in the maxilla was higher than that in the mandible[5,22]

TABLE 1: Oxford centre for Evidence-Based Medicine 2011 Levels of Evidence

Question	STEP 1 (LEVEL 1*)	STEP 2 (LEVEL 2*)	STEP 3 (LEVEL 3*)	STEP 4 (LEVEL 4*)	STEP 5 (LEVEL 5)
How common is the problem?	Local & current random sample surveys	A systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case series**	n/a
Is this diagnostic or monitoring test accurate? (diagnosis)	A systematic review of cross-sectional studies with consistently applied references standard & blinding	Individual cross-sectional studies with consistently applied references standard & blinding	Non-consecutive studies without consistently applied references standard**	Case-control studies or poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy (prognosis)	A systematic review of inception cohort studies	Inception cohort studies	Cohort studies or control arm of randomized trial*	Case series or case control studies, poor quality prognostic cohort studies**	n/a
Does this intervention help? (treatment benefits)	Systematic review randomized trials or n-of 1 trial	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow up study**	Case series or case control studies, historically control studies**	Mechanism based reasoning
What are the common harms? (treatment harms)	Systematic review randomized trials, Systematic review of nested case control studies	Individual Randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow up study provided there are sufficient number to rule out common harm**	Case series or case control studies, historically control studies**	Mechanism based reasoning
What are the rare harms? (treatment harms)	Systematic review randomized trials or n-of 1 trial	Randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow up study provided there are sufficient number to	Case series or case control studies, historically control studies**	Mechanism based reasoning

			rule out common harm**		
Is this (early detection) test worthwhile? (Screening)	Systematic review randomized trials	Randomized trial	Non-randomized controlled cohort/follow up study**	Case series or case control studies, historically control studies**	Mechanism based reasoning

*Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect sizes

** As always, a systematic review is generally better than an individual study.

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