Mini Review

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Interventions for preoperative children's anxiety

Abstract

Motivation/Problem Statement: This paper is around interventions for children preoperative anxiety. Preoperative anxiety is a common phenomenon that can result in an effect of a lifetime. Several interventions are available this days based on different studies; however, few studies have discussed the superiority of the different methods available. Therefore, the aim of this paper was to identify the effective intervention for children preoperative anxiety.

Approach/method: Research databases were sought for studies around interventions for preoperative children anxiety. The search was limited for articles published in English language in the last ten years, conducted on humans and randomized control studies. Critical Appraisal Skills Program (CASP) RCT framework is used to critically analyse and review each article. The four chosen studies were conducted in different countries in order to raise the generalisation of the paper.

Results: After critically appraising the four studies, the result was that still it cannot be definite which intervention method is the most appropriate to alleviate children preoperative anxiety.

Conclusion: In conclusion, there is a need for more studies to investigate the best intervention to alleviate children anxiety. More future studies will help to improve the current practice and will add to the evidence base practice.

Keywords: children, anxiety, operating room

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Abbreviations: CASP, critical appraisal skills program; RCT, randomised control trials; ASA, american society of anaesthesiology classification; OR, operating room

Introduction

Preoperative anxiety is a common phenomenon; up to 60% of children undergoing surgical operations feel stressed or anxious.[1,2] These feelings could be a result of being away from their parents, the surgical environment that children are not familiar with, or a reaction to being with strangers.[3] Pain perception is also something that can increase if a child is anxious.[4] This may result in unpredictable behaviours from the child and reduce their cooperation. Additionally, it could increase the rate of adverse effects on the cardiovascular system of the child,[5] which can lead to the failure of an operation or its being postponing. Additionally, bad hospital experiences can have long-term psychological effects on a child's life such as bed-wetting, nightmares and negativity.[6] Therefore, it is essential to reassure children in the perioperative period and try to make them feel calm through suitable interventions.

This assignment will attempt to identify the effective intervention to reduce children's anxiety during the preoperative period. This is achieved by critiquing four articles that evaluate different methods of decreasing children's anxiety. In order to assess and analyse each article critically, the Critical Appraisal Skills Program (CASP)[7] RCT framework was used throughout this assignment.

Materials and methods

PubMed and Medline via Ovid Databases were used within this assignment to search for relevant articles and the keywords used were "children", "anxiety" and "operating room". The exclusion criteria adopted were "articles published in the last 10 years" to find recent evidence-based practice, "humans" for ethical purposes, "English language" due to insufficient time for translating and "clinical trial" as it is considered the gold standard for clinical evidence when conducted properly.[8] After reviewing the resulting articles and a quick but focused scanning of their abstracts, four articles conducted in different countries were chosen because they were found more relevant to answer the research question.[9-12]

Results and discussion

All four articles' authors conducted randomised control trials (RCT) with similar yet focused aims using different intervention methods. Kain et al.[9] conducted a trial in New Haven on 58 children to evaluate the presence of one or two parents to reduce the child's anxiety preoperatively. In contrast in Florida, Golan et al.[10] evaluated whether trained professional clowns would be effective in reducing the anxiety of 65 children. In Iran, Hosseinpour and Memarzadeh,[11] sought to evaluate if a playroom with 200 children participating, would be more efficient in reducing child anxiety. Finally, in Italy, Vagnoli et al.[12] study included 75 children to compare whether pharmacological interventions were superior to non-pharmacological ones.

In each of the four studies, the relevant ethics committee had given. All of the researchers had also obtained signed consent forms from the children's parents. Such ethical considerations are essential when conducting any research[13] with Newell and Burnard[14] additionally stating that it is important to provide sufficient information to the study population and to give them the choice of accepting or refusing to be included in the study. Confidentiality of participants and evaluators is also important to raise the study validity and reliability.[15] Such as, in Golan et al.[10] study, where the researchers have used videotaped to rate the children's anxiety. However, they have still maintained the confidentiality of the study evaluators. Overall the methodology sections were well presented by authors in their studies, as recommended by Kothari.[16] The reader can easily distinguish the details of the study design, the process involved and how the data were gathered, including the measuring tool used and the defined time for each intervention and evaluation.

Study design is the frame work authors follow to identify the connections between variables and it gives an insight into the philosophical stand point from which a given study is being conducted.[17] In the chosen studies, the design was an RCT. According to Crombie,[18] RCTs are the best design choice to evaluate which intervention is superior to another. Moreover, RCTs are at level II in the hierarchy of evidence levels.[8] However, it could be argued whether RCT was an appropriate design for the studies. This is because using an RCT design suggests an empirical, positivist approach using deductive logic. Thus it is more commonly used for drug charts studies. An alternative approach would have been to use a qualitative approach, such as observation, in depth interviews, or a focus group, to gather data about the children and parents' lived experiences and their own perceptions. Such an approach would, as LoBiondo-Wood and Haber[19] notes, still have enabled a hypothesis to have been developed. Indeed, that the primary outcome of the four studies was to evaluate the children anxiety, such concerns could readily have been qualitatively assessed using both closed and open-ended questionnaires.[20]

Ajetunmobi[21] suggest that sample-size calculation is an important consideration to take account of before a study starts so that the sample size needed to determine statistical significance if it exists. Bowling and Ebrahim[22] concur, additionally declaring that including details of the calculation performed shows that a study has a representative sample; which is a necessary prerequisite if the study is to generalise its findings. Hosseinpour and Memarzadeh[11] based their sample size calculation on two research books that discuss this consideration and resultantly determined a requirement for 200 children. In contrast, the sample calculations undertaken by both Kain et al.,[9] and Vagnoli et al.[12] were based on previous studies that had statistically significant differences. Thus, their studies had smaller samples to that of Hosseinpour and Memarzadeh's.[11] However, a small sample size can, as Ajetunmobi[21] notes, have disadvantages, of there is a higher chance of a type II error. Type I is the false-positive finding while type II is the false-negative findings of a study. Type II errors can be avoided by adding more participants than the required number to ensure that even if a dropout occurred the study will not lose its power.[23] Thus, even though there was no dropout in the study of Vagnoli et al.,[12] it is still not obvious how the authors sought to avoid this error. However, it is possible to declare that the three studies of Kain et al.,[9] Hosseinpour and Memarzadeh's[11] and Vagnoli et al.[12] included sufficient numbers of participants to enable their findings to be generalised.

This contrasts with the study of Golan et al.,[10] which does not mention how their sample size was calculated. Therefore, any generalisation of the outcomes within the study might lack validity. With regard to drop out, all the studies had their participants complete the whole trial, except in Kain et al.,[9] where three participants dropped out; one for language difficulties and two for refusing the treatment. This affected the sample size and made it a smaller sample compared to the other three studies. However, Greenhalgh[8] mentions that a small sample size can be accepted in RCT studies, because RCTs are often expensive and time-consuming. Nevertheless, that Kain et al.[9] explain why the respondents dropped out can be evaluated and that they were excluded as a further strength of the study as raised the study's transparency.

The recruitment process is well explained and justified in all four studies with clear inclusion and exclusion criteria. The strategy employed in each study was to include preoperative children undergoing general anaesthesia with American society of anesthesiology classification (ASA) I-II. However, there were still a few differences within the studies; Golan et al.[10] recruited 65 children within the age of 3-8 years, whereas Hosseinpour and Memarzadeh[11] recruited 200 children over 4 years old. In contrast, Kain et al.[9] research assistants have recruited 58 children who arrived with two parents; however, it was not specified or gives sufficient details of those assistants, which could raise the possibility of bias in their study. Additionally, Kain et al.[9] have not mentioned the age of children included within their study. Whilst Vagonli et al.[12] recruited 75 children within the age of 5 to 12 years old, undergoing minor day surgery only without giving any justification; this could lead to a risk of this study having a less representative chance of the population targeted. Furthermore, Vagnoli et al.[12] study had a supplementary consideration for population eligibility; only Italian children. However, they do refer to this so as to avoid any misinterpretation during the evaluation process.

All studies excluded children with major medical illness history, as this could have had a direct impact on the outcomes of the studies. This was beneficial as their exclusion criteria decreased the risk of having less representative sample of the targeted population.[21] Randomised sampling has the advantage of increasing a study's chances of having a representative population.[24] This is because it gives an equal chance to every eligible person in the population to be included.[21] All study samples were drawn from single children's hospitals. However, they were conducted in different countries.

A randomisation method also has the advantage of reducing risk of bias if conducted properly.[7] In these studies, the researchers give details of how patients were randomly allocated into two or three groups. However, in Hosseinpour and Memarzadeh[11] the authors based their participants' assignment on patient identical numbers. In contrast, the other three studies' participants were allocated using a computer-generated system. According to Ajetunmobi,[21] a computer-generated system is one of the recognised methods of randomisation that can eliminate the risk of bias and reduce its errors. Thus it could be claimed that Kain et al.,[9] Golan et al.[10] and Vagnoli et al.[12] have used a randomisation method better than Hosseinpour and Memarzadeh.[11]

Finally, regarding randomisation method, it should be noted that participant distribution was similar and fair in all studies. This is essential because it means that significant differences within groups relate to the intervention influence and not to any confounding factors.[21] However, the study by Hosseinpour and Memarzadeh[11] has a difference in the participants' gender characteristics, which could have an influence on the study outcome. However, this absence of homogeneity does not seem to have had an effect on the study outcome, which could be because herniorrhaphy, which was the common surgery within the population of the Hosseinpour and Memarzadeh[11] study, is more common with in males.

With reference to the conduct of RCT studies, Ajetunmobi[21] state that the blinding method must be explained. This is because there is a direct relation between the risk of observer bias and the blinding, as researchers/evaluators might judge participants before the evaluation/measuring process begins. The blinding is explained in all the articles, along with the different methods deployed. However, it could be argued that it is difficult to achieve blinding because of the nature of the intervention encountered.

Intervention methods are clearly explained and discussed in all the studies, including details of when interventions were made and how they were administered, together with the exact premedication dosage, if used. However, none of the studies mention if there was a follow-up evaluation. This could be due to their primary outcome, which was principally to alleviate preoperative anxiety, in addition to the fact that all the studies mention that their research end point was

the anaesthesia induction time. However, it would have been useful to know if the interventions had postoperative effects.

The outcome measurements in all four studies were by m-YPAS scale. This tool has been previously validated and reviewed by authors and found to be valid and reliable.[25] All the studies included sufficient details of their measurement process, including the time and place of evaluation process, in addition to the identity of those who performed the measurements, except in the study. In addition, all the studies employed suitable statistical tests for their data analysis. Kain et al.[9] used the t-test and Mann-Whitney U test, because they had both normal and abnormal distributed data. Golan et al.[10] used MANOVA and Vagnoli et al.[12] used Pearson's correlation coefficient, which is suitable analysis test among two variables.

It may also be noted that, in terms of statistical significance, the P-value is the probability of the result being due to chance and is considered the key-term to know if the intervention is useful.[26] All the studies found that individual anxiety levels decreased after the interventions. However, the studies also found that anxiety levels rose again during anaesthesia induction. Therefore, it can be concluded that statistically significant differences lasted only for short time periods, which is important to note because it can lead to query if it has real implications and clinically useful.

According to Tappen,[27] the results section of any study should be presented clearly, as the goal of any research study is to maximise the dissemination of its results. Overall, the result sections are well presented alongside previous studies that had similar or contrasting outcomes. Authors have used multiple tables and figures to clarify their results to the reader, which helps to present important details about their outcomes. In Hosseinpour and Memarzadeh[11] the result is that a playroom is an effective method to reduce children's anxiety. Nevertheless this could be limited to hospitals that have the financial possibility to build a playroom next to their operating room (OR). Hosseinpour and Memarzadeh[11] have stated that play rooms should be prepared with suitable inexpensive toys for children such as plastic dolls, paints and books. This is essential, as other studies that have evaluated the play room affect have found that board games such as chest were not suitable and did not accomplish the primary objective of reducing children anxiety and was rather suitable for the children parents. Also, it could be argued that playroom intervention would require specialised team in children's behaviour and emotions, which is considered as a limitation too as not all hospitals have professional children therapeutic team. Thus several factors need to be studied for applying this intervention.

The results of Golan et al.[10] study show that clowns have a significant effect on reducing children's anxiety. However, clowns intervention has similar limitation to Hosseinpour and Memarzadeh[11] suggested intervention, as not all hospitals can apply the clowns' interventions. This is because trained clowns are not available in all hospitals and not all hospitals could afford training professionals to be specialised clowns. Nevertheless, possible clown phobia should be taken in account. Thus clowns intervention could not be applied to all children without having history of the psychological status of children, which could take several weeks before the operation schedule to be conducted if not existed and to be prepared for each child. Golan et al.[10] have also stated that professional clown intervention was induced years ago in New York in 1986. However, in their result Golan et al.[10] have declared that the significant effect of the clowns' intervention was less when anaesthetic mask was applied to children. Thus the final conclusion of Golan et al.[10] study was that clowns intervention could alleviate children anxiety, however, this intervention would be limited to preoperative period effect only or the fact that professionals or medical trained clowns needs to be trained more in order to optimise the use of this intervention.

Table 1 Study information

Study author	Vagnoli et al.[12] study	Golan et al.[10] study	Kain et al.[9] study	Hosseinpour and Memarzadeh[11] study
Study design	**RCT**	**RCT**	**RCT**	**RCT**
Number of sites	One children hospital	One children hospital	One children hospital	One children hospital
Country	Italy	Florida	New Haven	Iran
Subjects age range	5-12 years	3-8 years	Not mentioned	Over the age of 4 years
Total number of subjects	75 children	65 children	58 children	200 children
Population in study group (N)	25 children	22 children	30 children	100 children
Intervention in study group	0.5 mg.kg-1 oral midazolam	0.5 mg.kg-1 oral midazolam	One-caregiver	Playroom
Loss of follow up	None	None	1	None
Population in control group (N)	25 children	21 children	28 children	100 children
Intervention in control group	Two clown and a parent	Trained clowns	Two-caregivers	Preoperative waiting hall
Loss to follow up control group	None	None	2	None
Population in third group	25 children	22 children		
Intervention in third group	One parent presence	No Midazolam or clown presence		
Loss to follow up third group	None	None		

Where as in Kain et al.,[9] no significance difference was recorded with regards to child anxiety dependent upon the presence of either two or one parent. However, have found that the presence of a second parent was beneficial for parents prospective. However, Kain et al.[9] have also declared that the relationship of parents could have influenced the outcome in several ways and that social support could be one the solutions. This is essential because parents' conflictscan have direct effect on the children's status. Therefore, Kain et al.[9] study

had several weaknesses, such as the fact that not all hospitals allow parents to be in the holding area or in anaesthesia rooms, as anaesthetists might not comfortable with the presence of parents during anaesthesia induction. Also the acknowledgement of the effect of parents' relationships leads to further recommendations and further studies to include parents' relationships evaluation.

In contrast, Vagnoli et al.[12] found that the intervention of clowns combined with the presence of parents was superior in reducing children's anxiety than a pharmacological intervention with the parents present. However, during the induction phase the significant difference had also changed and anxiety had risen as other studies. Also Vagnoli et al.[12] have recommended that future studies should concentrate on one intervention method to identify the essential intervention. As it could not be acknowledged whether the existed effect was from the clowns' intervention or the parents' presence.

Conclusion

In conclusion, the chosen studies show good evidence on which to base practice. The authors manage to answer their research questions with key recommendations to reduce children's anxiety. All the studies highlight the need for more studies to investigate the best interventions, bearing in mind the considerations and limitations discussed in previous studies. In addition, all the studies have strengths and weaknesses with some being more generalised based on either their sample size or having fewer limitations. Moreover, all studies were conducted in single hospital, which is considered, given the views of Polgar and Thomas,[28] a limitation shared by all the studies, which will lead to lack external validity. Therefore their study outcomes could be useful but should be considered with caution. As Moore et al.[29] declare, the effect of an intervention on a small sample might not be applicable to a larger sample. Thus, even if a study has statistical significance but is conducted in one site it can be questioned as to whether its results have true clinically significance. In this regard, although the study by Hosseinpour and Memarzadeh[11] had a larger sample size to the other three studies, their outcome remains limited to hospitals capable of building playrooms. With the final result being, therefore, after critically appraising all four studies, that one still cannot be certain as which intervention method is the most appropriate to alleviate children preoperative anxiety.

Implications/clinical implications

In general since several factors influence's children anxiety, additional studies is highly recommended and are needed to try to cover those factors. Future studies could study the common factors that raise the children anxiety and try to find solutions to resolve it. This would reduce the risk of those factors affecting the primary outcome of the study. Also researchers could include the anaesthesia induction phase in their studies to get a better beneficial effect. Especially that most studies have acknowledged that the children anxiety was higher during induction phase. Thus special consideration should be noticed to find interventions suitable within the anaesthesia induction period.

Hospitals should be encouraged to implicate interventions to alleviate children with caution to what is individually suitable for potential admitted children. Raising the healthcare professionals awareness about the issue of children anxiety is also useful and would improve their practice and patient services provided. A pre-evaluation might be one of the solutions to prepare children for the perioperative phase. Thus implementing team training would have significant effect. Organisational culture within the perioperative area needs also to be changed and developed to have substantial effect.

Finally, international policies and guidelines would be very beneficial to be adopted and adhered, alongside an agreement to implicate interventions suitable and specifically for children anxiety. Developing a training for all staff involved within the preoperative and intraoperative periods and re-evaluating staff trained and improving their current practice would also have big difference and would eventually help to reduce children anxiety.

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Conflicts of interest

The author declares that they have no conflict of interest.

Limitations

This study has looked at four studies that used RCT as their study design and is a limitation to be declared. Another limitation could be the sample size of three of the study and that all studies were conducted in a single centre.

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