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SCIENTIFIC REVIEW

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Aids to improve understanding of statistical risk in patients consenting for surgery and interventional procedures: A systematic review

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Abstract

Background: Informed consent is an essential process in clinical decision-making, through which healthcare providers educate patients about benefits, risks, and alternatives of a procedure. Statistical risk information is difficult to communicate and the effectiveness of aids aimed at supporting this type of communication is uncertain. This systematic review aims to study the impact of risk communication adjuncts on patients' understanding of statistical risk in surgery and interventional procedures.

Methods: A systematic search was performed across Medline, Embase, PsycINFO, Scopus, and Web of Science until July 2021 with a repeated search in September 2022. RCTs and observational studies examining risk communication tools (e.g., information leaflets and audio-video) in adult (age >16) patients undergoing a surgical or interventional procedure were included. Primary outcomes included the objective assessment of statistical risk recall. Secondary outcomes included patient attitudes with respect to statistical information. Due to the study heterogeneity, a narrative synthesis was performed.

Results: A total of 4348 articles were identified, and following abstract and full-text screening 14 articles, including 9 RCTs, were included. The total number of adult patients was 1513. The most common risk communication tool used was written information ($n = 7$). Most RCTs (7/9, 77.8%) showed statistically significant improvements in patient understanding of statistical risk in the intervention group. Quality assessment found some concerns with all RCTs.

Conclusion: Risk communication tools appear to improve recall of statistical risk. Additional prospective trials comparing various aids simultaneously are warranted to determine the most effective method of improving understanding.

KEYWORDS

decision aids, health literacy, informed consent, patient communication, surgery, visual aid

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1 | INTRODUCTION

Informed consent represents an essential process in clinical decision-making, through which healthcare providers educate patients about the benefits, risks, and alternatives of a given procedure. Statistical risk information pertaining to medical procedures is by nature probabilistic and can be difficult to communicate. Healthcare professionals typically narrate the chance of a complication occurring in descriptive terms (e.g., “rare”) or as percentages/proportions. However, narrating the statistical chances of a complication occurring in these ways may be fraught with pitfalls, in part due to the limited numerical literacy among surgical patients. A recent meta-analysis of 18,895 surgical patients from 40 studies found that 31.7% patients were classified as having limited health literacy as measured by a number of validated and non-validated tools.[1] Limited health literacy among surgical patients was not found to be related to surgical specialty, age, or education.[1] Numeracy, defined as “the ability to understand and use numbers in daily life”,[2] is often poor among the general population, with most adults having difficulty converting small frequencies such as “1 in 1000” to 0.1%).[3]

Patients' numeracy are not routinely evaluated nor is the presentation of information adapted to their educational level. There is also considerable variation regarding how numerical probabilities are translated into verbal probabilities (e.g., negligible or low) among clinicians.[4] In addition, the recall of surgical complications following consent is poor.[5,6] Even for those with adequate statistical understanding, relating objective probabilities in a personal way is difficult and often requires additional heuristics to facilitate greater understanding.[7] An understanding of each individual statistical risk is vital as individual patients may attach different thresholds to each individual risk rather than the overall statistical risk of having any complication. Taking these different thresholds into consideration facilitates shared-decision making in which patients are the experts of their own values. However, at present few strategies aimed at implementing shared decision-making report the provision of information relating to the risks of a procedure.[8]

Decision aids are described as “means of helping people make informed choices about healthcare that take into account their personal values and preferences”[9] and may help in the communication of statistical risks in the form of risk communication tools. Such tools include audio/video tools, written information, and visual aids (Table 1, **Online Resource 1**). While they have previously been used in screening or communicating risk of disease,[10] it is unclear to what extent they are used for patients' consenting for surgery. Surgery, for many, is an event that carries significant emotional burden, and aids, which can help navigate the intended treatment and therefore have clear potential. Various aids have been studied in relation to patients' understanding of surgical procedures, with one simulated study of visual aids for statistical risk information finding greater acceptability among participants.[11–15] However, many of these studies measure patients' ability to recall complications without their associated statistical risk.

TABLE 1 Glossary of terms contextualized for this study.

Term	Definition
Complication	Any untoward event occurring as a result of surgery or interventional procedure which has a negative impact on a patient's health and wellbeing
Statistical risk	The probability or chance of a complication occurring during a surgical or interventional procedure
Decision aid	Tools to facilitate shared decision-making about health care options; providing information on options and helping patients clarify, and communicate the personal value they associate with different features of the options[48]
Risk communication tool	An instrument and type of decision aid, which helps facilitate patient communication regarding statistical risks (online resource 1)

While the effectiveness of statistical risk communication methods has been compared in medical populations,[16] and a recent review[17] demonstrated that communicating personalized risks in surgical patients may improve information provision, no review has focused on broader risk communication tools in surgery. To that end, this systematic review aims to study the impact of aids and other risk communication adjuncts on understanding and perception of statistical risk in patients undergoing surgery and consent-requiring interventional procedures.

2 | MATERIAL AND METHODS

This study was reported in line with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guideline[18] and registered on PROSPERO (CRD42022285789).

2.1 | Search strategy

2.1.1 | Eligibility criteria

Eligibility criteria was developed using the population, intervention, comparator, and outcome (PICO) framework. The population of interest were adults (age >16) undergoing surgical or consent-requiring interventional procedures. The latter is defined as procedures used for diagnosis or treatment that involve incision, puncture, entry into a body cavity or the use of ionizing, electromagnetic, or acoustic energy.[19] The "intervention" of interest was defined as a decision aid, tool, method, or consent adjunct aimed at improving understanding of procedural statistical risk information. Primary outcomes were the objective assessment of the recall, understanding, or perception of statistical risks. In the absence of defined methods for measuring this, we expected these to be knowledge questionnaires. Secondary outcomes included subjective outcomes, such as patient attitudes with respect to the statistical information provided. Observational studies discussing patients' knowledge of statistical risk were included to provide a general overview of statistical risk knowledge in surgical patients. Studies solely aimed at improving patients' understanding of nonstatistical aspects of a procedure were excluded.

2.1.2 | Information sources

A systematic search was performed by an academic librarian with over 20 years of experience on July 13, 2021. In total, five databases were included: Ovid Medline, Embase, APA PsychInfo, Scopus, and Web of Science. Results were de-duplicated and exported to EndNote X9.3.3. Additional articles were identified through the reference list of relevant reviews. Both English and non-English articles were included. Details of the search strategy used can be found in **Online Resource 2**. The search was repeated on September 5, 2022.

2.1.3 | Study selection

Abstracts of all articles were independently screened by two reviewers. Disagreements were resolved through discussion or a third reviewer. Full-text screening was performed in the same manner.

2.2 | Data extraction and synthesis

2.2.1 | Data extraction

Data from included articles were independently extracted by two individuals using a predefined data collection form. Data extracted included study design, sample size, age range, population, interventions, controls, outcomes, method of assessing understanding of statistical risk, and results relating to our review. A p-value <0.05 was considered as statistically significant for studies comparing differences and improvements between groups.

2.2.2 | Quality assessment

Randomized control trials (RCTs) were assessed using the Cochrane Risk-of-Bias Tool[20] with cross-sectional studies assessed using an adapted version of the Newcastle–Ottawa Scale.[21] The National Institutes of Health (NIH) quality assessment tool for before-after (pre-post) studies with no control group was used for relevant studies.[22] Two reviewers independently assessed the quality of the included studies using the relevant criteria with disagreements resolved through discussion. Certainty of evidence was assessed using the GRADE approach.[23]

2.2.3 | Data synthesis

A narrative synthesis was performed in accordance with the Synthesis without Meta-Analysis guideline.[24] This was chosen in favor of a meta-analysis due to heterogeneous outcome reporting. Studies were grouped based on the type of intervention used.

3 | RESULTS

3.1 | Identification of eligible studies

A PRISMA flow diagram summarizing our search results is presented in Figure 1 Our initial search identified a total of 4348 records, with a repeat search identifying one additional study. Following deduplication and screening, 14 studies were included. As one study included children, the total number of adult participants was 1513.[25]

3.2 | Characteristics of studies

The characteristics and outcomes of included studies are summarized in Table 2 and Table 3 Most of the studies were RCTs (n = 9, 64.3%), with the remainder being cross-sectional (n = 3, 21.4%) and before–after studies (n = 2, 14.3%). In addition to patients undergoing surgery, five consent-requiring interventional procedures were included.[26–29]

Interventions that were studied can be broadly divided into three types: (1) written information (n = 3, 25%); (2) graphical presentations of risk (n = 4, 33%), and (3) audio/video tools such as audio tapes or online videos (n = 1, 8.3%). Two studies (16.7%) compared multiple interventions: Shukla et al.[30] and Gett et al.[31] while two studies (25%) assessed a blended

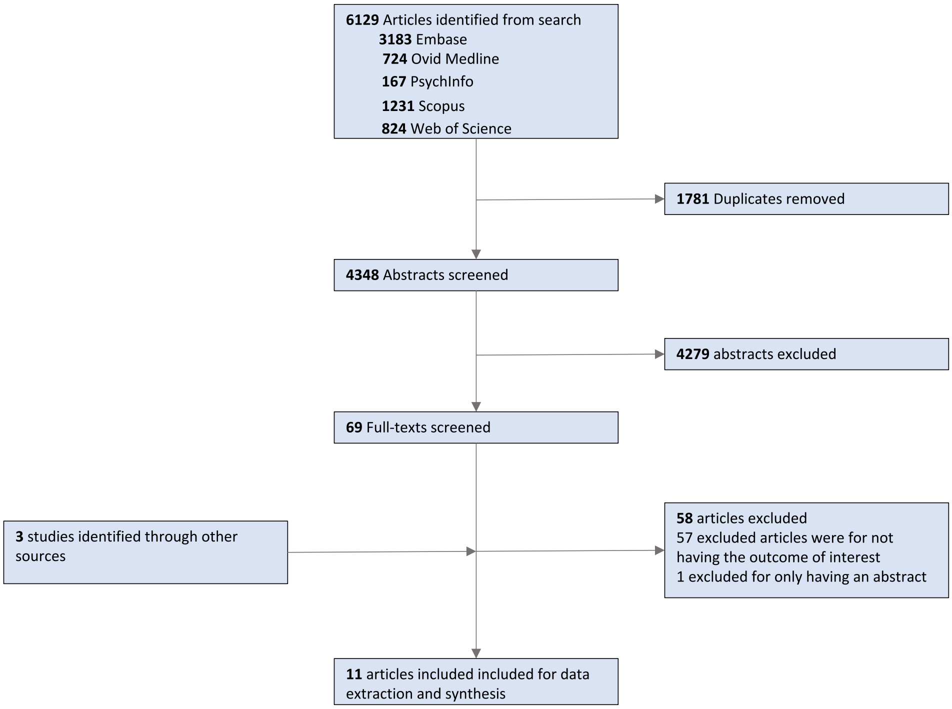

FIGURE 1 PRISMA flow diagram.

intervention: Laupacis et al.[32] and Inglis et al.[33] Where relevant controls generally received verbal discussions (*n* = 7, 70%) with others using written informed consent (*n* = 1, 10%),[26] "routine information" (*n* = 1, 10%),[32] and the same medium as the intervention with less information (*n* = 1, 10%).[33]

Most studies assessed the impact of interventions in improving patients' knowledge of a procedure through questionnaires with questions relating to statistical understanding. The number of questions requiring a patient to recall the probability of an event varied between studies from 1 to 12 questions (median = 2.5).[29,34–36] Other outcomes of relevance to this review included patients' preferred method of risk communication with patients being asked to rank the various methods.[31]

3.2.1 | Quality assessment

Some concerns were found with all RCTs (Figure 2), largely due to issues with outcome reporting including lack of statistical analysis plans and whether results relating to statistical risk understanding could be separated from overall knowledge, or with the reporting of the randomization process. The quality of cross-sectional studies ranged from unsatisfactory to satisfactory (Figure 3). Issues included a lack of a validated assessment measure (as expected) and information on non-respondents. The quality of before–after studies was better with both studies rated as good.

3.3 | Findings

3.3.1 | Written information

Seven studies utilized written information as a risk communication tool.[25,27,29,30,32,33,37] Three studies used written information as part of a blended intervention (described in the audio/video and graphics section of the results).[29,32,33] Winfield et al., Bhambhwani et al., and Alsaffar et al. compared the use of written information through patient information sheets against control groups receiving standard verbal information.[25,27,37] Winfield et al. and Bhambwani et al. both found statistically significant improvements in scores on questionnaires containing questions related to statistical risk in patients undergoing excretory urography (% mean difference = 25, *p*-value <0.01) and strabismus surgery, respectively (mean difference = 1.65, *p*-value = 0.044). Both studies' interventions were written information tools compared to control groups receiving verbal consent.[25,27] In contrast, Alsaffar et al.'s use of a written information tool for patients undergoing thyroidectomy led to no statistically significant improvements in the intervention group (% mean difference = 3, *p*-value >0.05).

Shukla et al. compared the use of a patient information sheet at different reading levels (second and eighth grade) against groups who received standard verbal information or an educational video. Patients using the second grade reading level information sheet group scored significantly higher on the

TABLE 2 Study design characteristics of included studies.

Study	Study design	Total sample size (control)	Mean (age range)	Procedure	Aid medium	Intervention	Control
Alsaffar et al.[36]	RCT	49 (25)	49.0 (27–77)	Total thyroidectomy	Written	Written information sheet + verbal consent	Verbal consent
Bhambhwani et al.[24]	RCT	28 (14), 21 children	45.8 (N/A), adults	Strabismus surgery	Written	Written information sheet + verbal consent	Verbal consent
Gett et al.[30]	Cross-sectional	32	48.3 (21–73)	Colonoscopy	Graphical	Graphical formats: Pie chart, 1000-person diagram (icon array), logarithmic scale. Text formats: Absolute risk ratio, relative risk ratio	N/A
Habib et al.[27]	RCT	200 (100)	68.8 (37–94)	Peripheral angioplasty	Graphical	Risk assessment chart (patient information sheet provided based on referral pathway)	Verbal consent
Hladkowicz et al.[37]	Before-and-after study	183 (90)	60.6 (N/A)	Elective major surgery (non-cardiac)	Graphical	Personalized risk calculator incorporating graphical displays (icon array)	Verbal consent
Inglis et al.[32]	RCT	40 (20)	46.5 (21–80)	Surgical procedures requiring general anesthesia	Written and audio/ video	Audiotape recording + written information sheet (with detailed information)	Audiotape recording + written information sheet (with routine information[a])
Laupacis et al.[31]	RCT	120 (61)	60.0 (20–81)	Elective cardiovascular surgery (CABG, valve surgery or combined)	Written and audio/ video	Audiotape + booklet.	Routine information[a]
Lee et al.[35]	Cross-sectional	126	53.2 (N/A)	Mastectomy	Unspecified	N/A	N/A
Lloyd et al.[34]	Cross-sectional	71	Unspecified	Carotid endarterectomy	Unspecified	N/A	N/A
Raymond et al.[33]	Before-and-after study	150	54 (N/A)	Pan-surgical	Graphical	Personalized risk calculator incorporating graphical displays (bar graph)	N/A
Schwalm et al.[28]	RCT	150 (74)	63 (N/A)	Coronary angiography	Written and graphical	Written decision aid incorporating graphical displays (icon array)	Verbal consent
Shukla et al.[29]	RCT	100 (25)	74 (N/A)	Cataract surgery	Written and audio/ video	Group 2: Verbal information + 2nd grade reading level written information sheet; group 3: Verbal information + 8th grade reading level brochure; group 4: Verbal information + patient education video	Verbal consent (group 1)
Winfield et al.[26]	RCT	80 (38)	N/A (19–68)	Excretory urography	Written	Detailed written informed consent form + interview	Verbal consent
Xia et al.[25]	RCT	205 (104)	43.3 (N/A)	ERCP	Audio/video	Patient education video detailing procedure + standard written informed consent	Written informed consent

Abbreviations: CABG, Coronary artery bypass graft; ERCP, Endoscopic retrograde cholangiopancreatography; RCT, Randomized controlled trial.

[a]Routine information describes where the control group was described as being provided information usually given for a procedure without a specified medium.

TABLE 3 Outcome measures of included studies.

Study	Statistical understanding or recall measures	Secondary (non-probabilistic) outcome measures	Study results summary
Alsaffar et al.[36]	12-Question MCQ (2 questions on statistical risk)	- Understanding of procedure - HADS	% Mean correct response: Intervention = 80, (range 35.3–94.2), control = 83 (range 25–100), p = NS
Bhambhwani et al.[24]	13-Question MCQ (3 questions on probabilities, with 3 on non-numerical likelihoods ("low", "moderate", etc.)	- Understanding of procedure	Mean correct response: Intervention = 5.79 ± 2.12, control = 4.14 ± 1.99, $p = 0.044$
Gett et al.[30]	3-Section questionnaire, with (2 questions on preference of adjunct and ease of understanding)	- Understanding of procedure	Risk communication format by preference (in order): 1. Pie chart ($n = 17$, 54.8%), 2. Absolute risk ratios ($n = 6$, 19.4%) 3. 1000-person pictograph ($n = 6$, 19.4%). By ease of understanding: 1. Pie chart 2. 1000-person pictograph
Habib et al.[27]	18-Question questionnaire (2 questions on statistical risk)	- Understanding of procedure - Procedure related outcomes (length, probability of success, use of sedation/analgesia	Patient understanding of procedural complications: Patients receiving visual aid[a] had a better perception of benefits ($p = 0.049$) but not risks ($p = 0.562$)
Hladkowicz et al.[37]	3-Question MCQ (2 questions on statistical risk)	- Patient satisfaction - STAI	Adjusted average increase in knowledge score = 14.3%; 95% confidence interval (CI), 6.5 to 22.0
Inglis et al.[32]	VAS containing verbally reported risk and numerical risk equivalents ("1:100", "1:2") (6 risks asked in total)	- STAI	% Of correct responses related to: Risk of death: - Intervention = 55%, - control = 15%, $p < 0.001$ Risk of serious damage to teeth: - Intervention = 15%, - control = 0%, $p < 0.001$ Nonsignificant differences in three other risk questions
Laupacis et al.[31]	8-Item questionnaire assessing statistical risk perception	- Understanding of procedure - Treatment preference - Decisional conflict scale - Decision making: Preferred role and satisfaction	Mean correct response (at baseline): Intervention = 4.3 ± 6.2, control = 5.6 ± 7.0 Mean correct response (at follow-up): Intervention = 21.5 ± 18.1, control = 7.0 ± 7.6 Difference between baseline and follow-up Intervention = 17.23 ± 19.5, control = 1.4 ± 9.9, $p = 0.001$
Lee et al.[35]	20-Item questionnaire (1 question on statistical risk)	- Understanding of procedure - Involvement in decision making	% Of patients able to correctly identify probability of major complication occurring in the first 2 years = 14.3
Lloyd et al.[34]	Questionnaire (3 questions on statistical risk, 1 on risk due to surgery)	N/A	Patients' mean % estimate (range) of stroke risk due to surgery = 10 (0–65) as compared to the actual local risk of 2%.
Raymond et al.[33]	12-Questions on the probability of various complications occurring using VAS	- Motivation to undergo operation - Anxiety and attitudes toward risk reduction	Overall, patients overestimated their operative risks with higher risk patients significantly more likely to

TABLE 3 (Continued)

Study	Statistical understanding or recall measures	Secondary (non-probabilistic) outcome measures	Study results summary
			underestimate their risk of different risks than the group as a whole. 93% of patients supported the use of the calculator as improving their understanding of risk
Schwalm et al.[28]	5-Question MCQ (1 question relating to statistical risk)	- Decision conflict scale - Knowledge - Informed value congruence - Clinical outcomes	Mean correct response: Intervention = 3 (95% CI = 2.6–3.3), control = 2 (95% CI = 1.7–2.3), $p < 0.01$
Shukla et al.[29]	12-Question MCQ (3 questions on statistical risk including two on risk)	- Patient understanding of their condition, the procedure, risks, benefits, and treatment alternatives	Mean score: Group 1 = 7.68 ± 2.80, group 2 = 10.8 ± 1.29, group 3 = 9.08 ± 1.60, group 4 = 10.56 ± 1.44 P (group 1 vs. 2) < 0.0001, p (group 1 vs. 3) > 0.05, p (group 1 vs. 4) <0.0001, p (group 2 vs. 3) < 0.0001, p (group 2 vs. 4) > 0.05, p (group 3 vs. 4) < 0.0001
Winfield et al.[26]	8-Question MCQ (2 questions regarding statistical risk)	- Incidence of adverse reactions - Degree of discomfort - Patient's anxiety before and after the procedure - The desirability of obtaining informed	% Mean correct response: Intervention = 73, control = 48 $p < 0.01$
Xia et al.[25]	8-Question MCQ on the probability of event occurring	- Time for informed consent, - Overall satisfaction, need for more explanation, understanding of benefits, and anxiety	% Mean correct response: Intervention = 57.6, control = 45.1, $p < 0.001$

Abbreviations: HADS, Hospital Anxiety and Depression Scale; MCQ, Multiple-choice questionnaire; NS, nonsignificant; STAI, Spielberger State-Trait Anxiety Inventory; VAS, Visual analog scale.

[a]A proportion of the control and intervention group received an additional written information sheet.

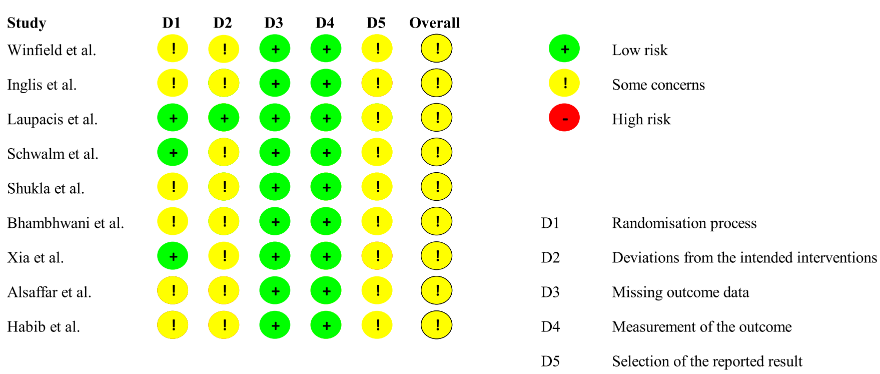

FIGURE 2 Consensus results of Risk of Bias 2 (RoB2) assessment for randomized control trials.

knowledge-based questionnaire than both the control group (mean difference = 3.12, p-value <0.0001) and eighth grade reading level information sheet group (mean difference = 1.72, p-value <0.0001). However, no statistically significant differences were found between the second grade reading level information sheet group and the educational video group (mean difference = 0.24, p-value >0.05).

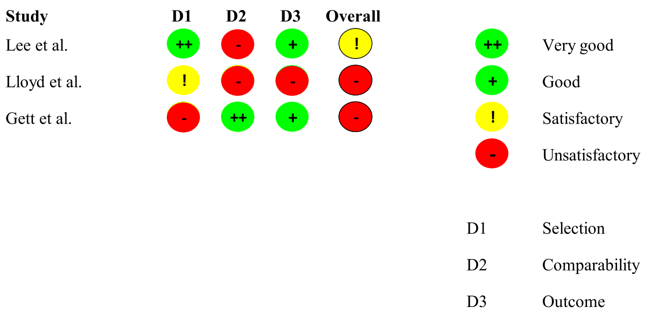

FIGURE 3 Quality assessment of cross-sectional studies according to modified Newcastle–Ottawa scale. “Unsatisfactory” studies are those scoring below 4, “satisfactory” studies score 5–6, good studies score 7–8 and finally “very good” studies would be scored 9–10. Online Resource 1: Examples of different risk communication tools. Figure designed using Flaticon.com with icons from Iakonicon and Dinosoft labs. * Paling perspective scale is a graphical method used to communicate risks [52]. Online Resource 2: Search strategy.

3.3.2 | Audio/video

Laupacis et al. utilized an intervention composed of an audiotape and written booklet and found that this group had statistically significant improvements in the ability to accurately recall the probability of complications occurring as compared to the routine information group (mean difference = 14.5, *p*-value = 0.001).[26] This difference was maintained at follow-up (mean = 10 days). Improvements were more limited in Inglis et al. who compared a blended intervention (audio recording with information sheet) but here the intervention groups were given the information at a greater level of detail. Statistically significant improvements ($p < 0.001$) were only observed for rarer complications (e.g., death, serious damage to teeth, etc.) with nonstatistically significant differences for other risks.[33] Finally, in a large study of 205 patients by Xia et al., participants were randomized to an intervention group receiving an educational video detailing endoscopic retrograde cholangiopancreatography in addition to the routine standard written informed consent or to a control group receiving the standard written informed consent alone.[26] Here, statistically significant improvements (% mean difference = 12.5%, *p*-value <0.01) were noted in the intervention group's ability to recall the statistical risks of the procedure as compared to the control group.

3.3.3 | Graphics

Gett et al.[31] asked patients to rank five methods of understanding for communicating risk based on their preferences and ease of understanding (1) absolute risk ratios compared to “everyday” risks (e.g., road traffic accident), (2) relative risk ratios compared to “everyday” risks, (3) pie chart, (4) 1000-person pictograph, and (5) a logarithmic scale. The pie chart and 1000-person pictograph were found to be significantly easier to understand than written forms of risk communication (absolute and relative risk) and the logarithmic scale. The most preferred risk communication format were pie charts followed by absolute risk ratios. Positive sentiment was also expressed in Raymond et al., where 93% of patients believed a personalized risk calculator presenting results as bar graphs improved their understanding of risk.[34]

In Habib et al, patients undergoing peripheral angioplasty were randomized to a group which had or did not have a risk assessment chart (incorporating icon arrays and a percentage scale), with a proportion of both groups receiving an additional patient information sheet. The risk assessment chart was found to significantly improve patients' perception of the procedural benefits but not complications. In Hladkowicz et al., a printout of personalized risk probabilities incorporating icon arrays improved knowledge by 14.3% compared to the control group.[38] Likewise, Schwalm et al.'s written decision aid incorporating icon arrays found significantly higher knowledge scores in comparison to those undergoing routine consent in an RCT of 150 patients.[29]

3.3.4 | Recall and perception of statistical risk in observational studies

Two observational studies assessed patients' recall of statistical risk. Lee et al. found patients' knowledge about complications for mastectomy was especially low with only 14.3% being able to accurately recall the correct probability of a major complication, with most underestimating the actual risk.[36] Lloyd et al. found that patients were also inaccurate about the stroke risk associated with carotid surgery with 23% of patients unable to answer the question. Patients significantly overestimated the risk of stroke, with larger estimations closer to the date of their procedure.[35] Similarly, Raymond et al. found the personal risks estimated by patients themselves were generally greater than the risks calculated by their electronic calculator.[34] Conversely, patients at higher risk of complications underestimated their personal risks.

4 | DISCUSSION

4.1 | Summary

We present a systematic review of interventions aimed at improving statistical understanding of risk in patients undergoing interventional procedures. Overall, studies were heterogeneous in terms of intervention and outcome assessment. Across the cross-sectional studies, patients' knowledge of statistical risk was poor. The majority of RCTs concluded that written or audio/visual aids could improve patients' ability to recall statistical risk, with quasi-experimental studies incorporating graphical representations yielding similar results. Other than a few studies which addressed this exclusively, this was based on a limited set of questions.

No specific type of communication medium can be concluded as being the most effective with only one study comparing multiple aids finding no statistically significant differences between the video and written information group.[30] Although there was limited evidence of patient preference for risk communication tools, one moderately sized cross-sectional study found preferences for pie charts over absolute risk ratios and pictographs.[31] Limited evidence suggests that risk communication tools may improve long-term retention[32] and greater recall for more serious complications, such as death.[26,27]

4.2 | Study quality

Outcome measurement between studies was variable, with large differences in the number of questions relating to statistical risk. Furthermore, not all studies analyzed these questions separately from overall knowledge. Differences in knowledge scores may therefore be attributable to the knowledge of other aspects of the procedure. Despite this limitation, three studies that analyzed statistical risk recall as their sole outcome found statistically significant improvements among the intervention groups.[26,32,33] Although the study size varied considerably (28–205 patients), the two largest trials, Xia et al. and Habib et al., with 200 and 205 patients, respectively, both found significant differences in statistical recall in patients utilizing a risk communication tool though for the latter this was for benefits of the procedure and not risks.[26,28] Certainty of evidence was downgraded due to concerns in the risk of bias assessment of studies and indirectness of certain studies where questions relating to statistical risk was not analyzed separately. This led to a final rating of low quality (Table 4).

4.3 | Interpretation and context

The importance of disclosing risks relevant to the individual patient has grown in the United Kingdom since Montgomery v Lanarkshire Health Board, where a patient was not sufficiently warned of the risk of shoulder dystocia during vaginal delivery, which resulted in their child being born with cerebral palsy.[39] The ruling found that doctors must provide information on all risks to which a reasonable person in the patient's position would attach significance.[39] A similar ruling has existed in the USA since 1972 following Canterbury v. Spence where a patient was not sufficiently warned of the risk of paralysis.[40]

Poor understanding of statistical risk is likely multifactorial, with clinicians either not disclosing the associated statistical risks or failing to do so in a manner that is understood by patients due to low numeracy. Risk communication tools are ideally placed to tackle both issues. Risk communication tools could act as a reminder of complications discussed through specifying risks that need to be discussed for a particular procedure, reducing variation between clinicians. Flexibility in how they are presented (i.e., the medium used) allows patients to find the explanation best suited for their own individual needs potentially overcoming issues with low numeracy. The extent to which they are used in actual practice is unclear. However, they could be implemented at multiple timepoints in the consent process. Providing information prior to consenting patients may guide discussion, while providing information after will allow them to reference information continuously. The ability to recall information has been shown to decrease over time with only one included study measuring outcomes at two timepoints and demonstrating better retention of statistical risk at follow-up.[32,41,42]

In studies that assess the recall of procedural complications without probabilities, the provision of information in written or video form improved patient recall.[11,43,44] By including statistical information, consent aids may go further in helping patients weigh up their decision to undergo a procedure. Managing pre-procedural expectations, including complications, is directly relevant to patient outcomes following surgery. Fulfilling patient expectations has shown some association with improved patient-reported outcomes,[45] while

TABLE 4 Certainty of evidence for our outcome using GRADE.

Outcome	Number of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Certainty
Recall/knowledge of probabilistic risk	9	RCT	Serious	Not serious	Serious	Not serious	⊕⊕◯◯ LOW

understanding that things may go wrong can help manage anxiety and distress if a complication occurs.

Clinicians may not provide probabilities of complications occurring for fear as it may cause unnecessary anxiety with implications for post-operative recovery.[46] Some mismatch between the level at which surgeons and patients deem necessary to disclose has previously been found.[47,48] Though not one of our outcomes, six studies measured patient anxiety, with five finding no significant difference between the intervention and control groups,[26,27,33,37,38] and one study reporting decreased anxiety in most patients.[34] This suggests that clinicians can disclose the necessary information regarding statistical risk without fear it may cause anxiety in patients.

Electronic consent (eConsent) forms represents a multimodal method of consent that has been shown to improve the quality of documentation in surgical consent.[49] In the future, audio-visual tools providing procedural information alongside interactive functionality could be directly embedded within an eConsent form for ease of viewing, thus presenting an advantage over existing printed patient information sheets. Videos embedded in eConsent forms has previously been shown to enhance understanding in research settings.[50] Like audio-visual tools, eConsent would be ideally placed to incorporate personalized risk communication formats, allowing patients to readily choose from a range of formats according to their preference and ability.

Since an adequate level of numeracy and appropriate heuristics are required to navigate statistical information, surgeons and interventionalists should be aware of their patient's level of numerical literacy, with one study demonstrating information delivered at a lower reading level led to greater statistical risk recall.[30] Icon arrays are another tool shown to specifically help communicate medical risk to patients with low numeracy.[51] Patient preferences for their method of risk communication should also be considered rather than adopting the same approach for each patient, though only one included study assessed patient preference and without any objective measurement of improvements in recall.[31] Those seeking to utilize risk communication formats could consider combining the various mediums discussed in this review rather than individual interventions. For example, the incorporation of visual representations of risk such as icon arrays into written information sheets or provision of both a video and written information may have greater effectiveness. However, none of the included studies compared such blended interventions with single-medium interventions.

4.4 | Strengths and limitations

Strengths of our review include a comprehensive search of five databases and a diverse range of specialties and decision aid methods represented. However, due to our definition of “intervention” we have also included studies closer to medicine and radiology. Furthermore, our search did not include qualitative or mixed-method studies, resulting in a lack of subjective outcomes relating to patient sentiment toward risk communication. There was also significant diversity in terms of outcome measurements and reporting. As a result, we were unable to perform a meta-analysis to quantify the effects of different tools. Due to limited sample sizes across studies and a lack of information on baseline health literacy, we are unable to determine if particular interventions are better suited for different subgroups of patients.

5 | CONCLUSION

This systematic review found evidence that risk communication tools can improve patient understanding of statistical risk. However, given concerns with study quality these findings should be treated cautiously. Future research should aim to compare multiple communication methods in a single population to determine the methods, or combination of methods, patients respond to the most. Although we are unable to determine the single most effective tool, risk communication tools should be implemented in clinical practice, with the caveat that the most effective tool is likely to depend on the patient's needs, such as their level of education or health literacy and any existing sensory impairments, and their individual preferences.

AUTHOR CONTRIBUTIONS

Arif Hanafi Bin Jalal: Conceptualization; data curation; formal analysis; investigation; methodology; writing – original draft. **Despoina Chatzopoulou**: Conceptualization; data curation; formal analysis; investigation; methodology; writing – original draft. **Hani J Marcus**: Conceptualization; supervision; writing – review & editing. **Anand S Pandit**: Conceptualization; supervision; writing – review & editing.

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CONFLICT OF INTEREST STATEMENT

We declare no competing interests.

DATA AVAILABILITY

Data availability is not applicable as no new data or datasets were created.

ETHICS STATEMENT

No ethical approval was sought as this paper reviewed and analyzed previously published data.

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