Informed consent when prescribing medication:
a randomized controlled trial

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Methods

• Primary Outcomes
  • Percentage of risks recalled between 14-21 days after consent for treatment obtained (telephone questionnaire)
    1) Unprompted recall: Response to open-ended questions about risks that were discussed
    2) Prompted Recall: Response to closed-ended questions about risks (a list was recited to patient)

• Secondary Outcomes
  • Recall of each individual risk

• Statistical Analysis and Sample Size
  • Wilcoxon rank sum test for risk recall between groups
  • Participants excluded if it was clear that they had read responses directly from the handout (i.e. recited it verbatim for open question) for data shown

• Results minimally changed when data analyzed with these patients included (intention-to-treatment analysis)
• Sample size/power calculation: 22 per group required to show an average difference of 1 of 10 risks recalled between groups (two-tailed α=0.05, SD=1)

Discussion & Limitations

• Informed consent is important for all treatment interventions
• Risk recall was poor for both groups at two to three weeks
• Risk recall is minimally augmented by patient handout: e.g. 38% of patients did not recall discussing the risk of avascular necrosis of the hip
• Patients may have all the information required to make a treatment decision, but later forget that they were informed of risks when a devastating complication arises

• Limitations:
  • Only one physician (but this ensured consistency between groups)
  • Power calculation based on primary outcomes–lacked power for secondary outcomes

Conclusion

• This study provides high quality evidence that patients recall very few medication risks discussed with their physician shortly after the informed consent process even when a handout detailing the risks is provided.
• This has implications for patient care and medico-legal proceedings.

References