Clinical Validation of Medical Simulation:
A tale of two simulators- lessons learned
MICCAI 2003 Tutorial

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SIMULATION WILL BE READY FOR PRIME TIME ONLY WHEN PROPONENTS CAN SHOW THAT CLINICALLY USEFUL LEARNING RESULTS FROM SIMULATOR USE!!

Learning a New Language

- Face Validity
- Content Validity
- Predictive Validity
- Construct Validity
- Concurrent Validity
- Reliability
- Test-test Reliability
- Inter-Rater Reliability
- Convergent Validity

Face Validity

- The ability of the simulator to accurately provide a training/testing environment to measure knowledge skills and abilities
- Does it do what it is supposed to do?

Convergent Validity

- The degree in which the simulation experience is similar to real life.
- Does the simulator create an authentic and realistic experience.

Content Validity

- Does the simulator accurately measure the same KSA's as the current "gold standards"

Predictive Validity

- Can the simulator accurately predict proficiency in the real world.
- Will they perform as advertized?

Construct Validity

- Does the simulator actually measure the skill level?
- Can you show a difference between a novice and an expert?
- Seeks agreement between theory and practice.

Criterion Validity

- Will the use of the simulator help develop the skills needed to meet the criteria.
- ie will training on a simulator result in competence in real world application?

Reliability

- Consistency, Repeatability, and reproducibility of performance and skills while using the simulator.

Test-retest reliability

- Can the student maintain the skill over time/retesting?

Inter-rater reliability

- Will the evaluators "see the same thing" when evaluating the subjects performance.

Designing a validation Study for simulation

- Need clear (unambiguous) definition of what constitutes error and success for the procedure.
- Need high inter-rater reliability

Questions

- Can Simulator training provide an equal or better training experience than what is currently available?
- How do incorporate appropriate simulators into curricula?

Choice of procedure for simulation

- Common procedure
- High stakes
  - Consequences severe if done wrong
  - Time sensitive
- Limited opportunity for training

Chest Tube Placement Necessary And Life Saving Skill

How are Medical Students Taught to Insert Chest Tubes

- Standard Curriculum (USUHS)
  - Place 1 CT on Pig as MS3
  - Place 1 CT on Goat as MS4 (ATLS)
- Very Rare for student to place tube on human during clinical rotation

VIRGIL: Validation of a Chest Tube Simulator

Simulation for Medical Training – MICCAI 2003

VIRGIL

Simulation for Medical Training – MICCAI 2003

Validation

- Will Simulator training provide an equal or better training experience than what is currently available?
- Study designed to compare Virgil to Pig for teaching Medical students to insert a chest tube

Design

- IRB approval
- 20 third Year medical students starting surgery rotation
- All True novices – never seen one , never done one
- Knowledge & Perception questionnaire given
- Randomly divided into two groups of ten

Group 1 – Virgil Trained

- 10 Medical Students taught in standardized fashion (technique reviewed and corrections made as needed) to insert a chest tube on Virgil

Group 2 – Pig Trained

- 10 Medical Students taught in standardized fashion (technique reviewed and corrections made as needed) to insert a chest tube in an anesthetized pig

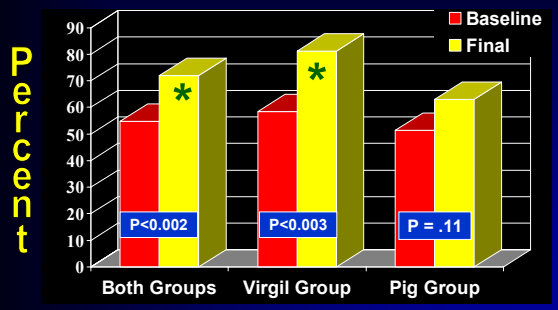
Testing on Virgil

- After Initial Training, both groups place CT in Virgil twice without coaching or instruction
- Time for chest tube insertion, proximity to organs, and complications recorded

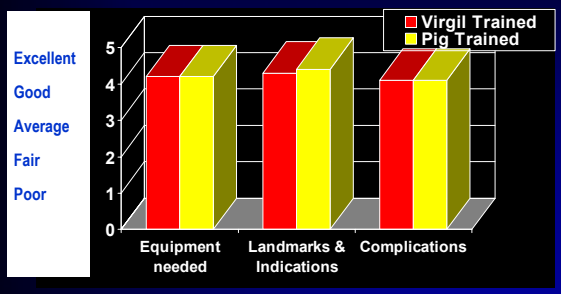
Evaluation by "experts"

- On separate day as part of normal curriculum all students insert CT into a Pig
- Instead of teaching the skill, faculty assigned to each table and blinded to teaching method silently evaluate performance without correction
- Students given final knowledge & perception questionnaire

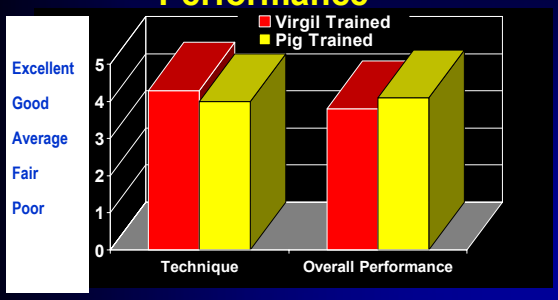
Test of Chest Tube Knowledge



Faculty Evaluation – The Student Is Able to Discuss:



Faculty Evaluation – The Students Technique & Overall Performance



Summary of Results

- Basic CT Knowledge improved in both groups (> Virgil)
- Students Comfort level improved significantly in both groups
- VIRGIL HAS GOOD FACE VALIDITY
- Also has excellent Convergent Validity – realistic experience

Summary of Results cont

- No faculty rated difference between groups for understanding of equipment, landmarks, indications, or complications (Content Validity)
- Faculty eval of technique & overall performance did not differ between groups (Content Validity)

Summary of Results Cont

- 75 % of students felt capable of inserting CT in austere environment after limited training
- Time for chest tube insertion on Virgil decreased with practice and did not differ from “experts” after second testing attempt (Construct Validity)

Conclusion

- In this study, Virgil was at least equivalent to the Pig for training Medical students to insert a chest tube.

SimPL

Diagnostic Peritoneal Lavage Simulator

VALIDATION STUDY

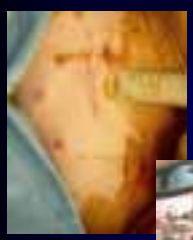
VALIDATION STUDY

SimPL vs. Pig for teaching DPL

SimPL Validation Study Design

- 40 Third Year Medical Students who were all true novices (never done one, never seen one)
- Randomly divided into two groups of twenty

Pig Group (n=20) trained to do DPL on a pig



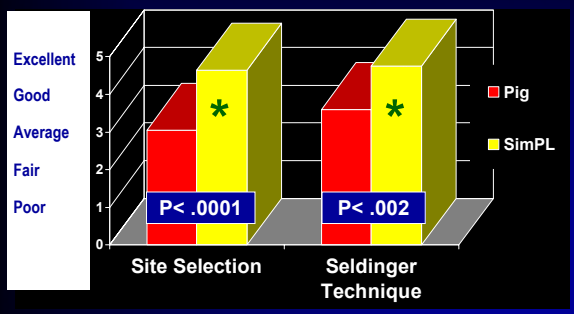
Sim Group (n=20) trained to DPL on VR DPL simulator- SimPL

DPL Validation Study Design (Cont)

- Both groups "tested" on ATLS® "standard" Traumaman™ Mannequin

Performance on Mannequin evaluated and scored by two trauma surgeons blinded to initial mode of training.

Faculty Evaluation: Student Performance



Summary of Results DPL Validation Study

- Knowledge increased significantly in both groups over baseline (p <.0001) Good Content, Face, & Convergent Validity
- Students self reported level of comfort increased in both groups (p<.0001)but more so in the Simulator trained group (p<0.01)

Summary of Results DPL Validation Study – Cont.

- Students who trained on the Simulator had significantly increased performance on site selection (p<0.0001) and understanding of the Seldinger technique (p<0.002)
- Evaluators had greater faith in ability of Simulator trained students to perform procedure after training (90% vs 60%)
- There was good Inter-Rater Reliability

Lessons Learned

- Many of our "gold standards" are not validated
- There are no widely established standards for validation of medical simulators (need for VMAS)
- IRB's not familiar with validation

IRB APPROVAL
Medical Students