The Regional Anaesthesia for Painful Injuries after Disasters (RAPID) Study: a randomized controlled trial protocol and analysis of training of Médecins Sans Frontières responders as trial proceduralists

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Introduction

- Lower extremity trauma during earthquakes accounts for the largest burden of geophysical disaster-related injuries
- Insufficient pain management is common in disaster settings, and regional anesthesia (RA) has the potential to reduce pain in injured patients beyond current standards.
- RA can be administered using either anatomic landmark or ultrasound (US) guidance; however no high-quality evidence on the use of RA in a acute humanitarian response settings performed by generalist response providers exists.

Objectives

RCT: To evaluate whether RA, either performed with or without US-guidance, by generalist response providers can improve analgesic treatment for earthquake-related lower extremity injuries in an acute response settings

Training: To evaluate knowledge attainment and skills acquisition among General practice Médecins Sans Frontières (MSF) volunteer response providers given focused training

Training Methods

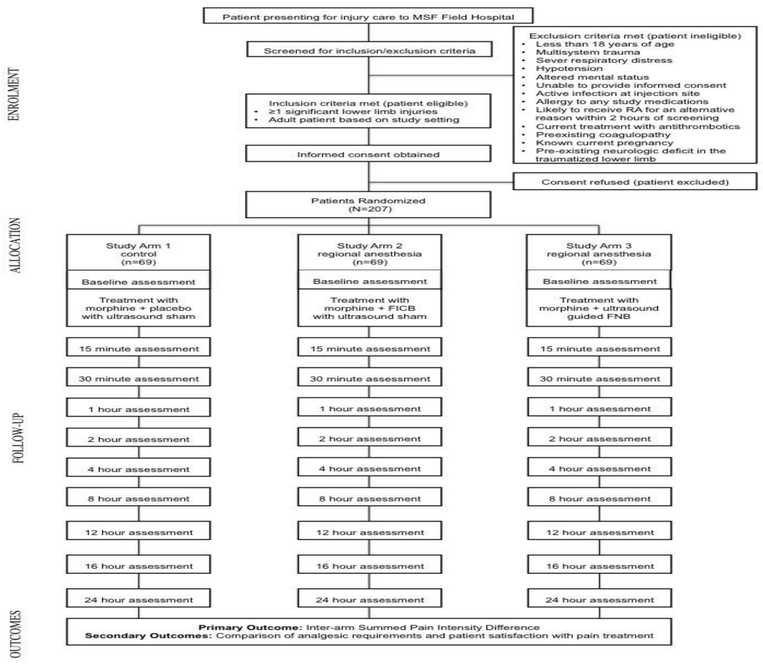
-MSF generalist humanitarian healthcare responders, including both physicians and nurses, were trained in USGFNB & LGFICB techniques using didactic sessions and interactive simulations during a one-day focused course.

-Outcome measures evaluated interval knowledge attainment via pre- and post-test evaluations and procedural proficiency was evaluated through monitored simulations, with performance of critical actions graded by independent observers.

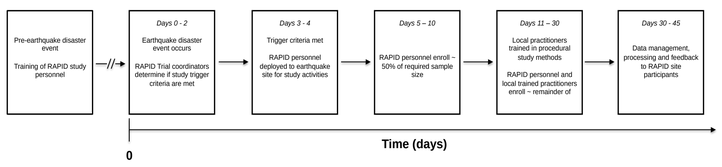
Design & Results

RCT Protocol

Flow Diagram



Timeline



- Immediate aftermath of a major earthquake in a LMIC with study initiation within 72-96 hours of disaster event
- ~45 days for study completion post event

Population: Prospectively enrolled victims with serious lower extremity injuries

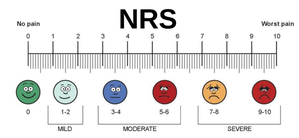
- *Inclusion:* Adults with ≥1 lower extremity injury presenting to the MSF field hospital
- *Exclusion:* multisystem trauma, clinical instability, active infection at the sight of injection, known current pregnancy, allergies to study medications, preexisting coagulopathy, likely to receive RA for alternative indication

Procedures:

- RCT with 1:1:1 allocation
  - Control: standard care (parenteral morphine, 0.1 mg/kg)
  - Study Arm 1: standard care + landmark-guided fascia iliaca compartment block (LGFICB)
  - Study Arm 2: standard care + US-guided femoral nerve block (USGFNB)
- Blinding eith US sham activities and placebo injections
- General practice MSF volunteer response providers trained using a focused protocol will perform the nerve blocks using 0.5% levobupivacaine 20 ml

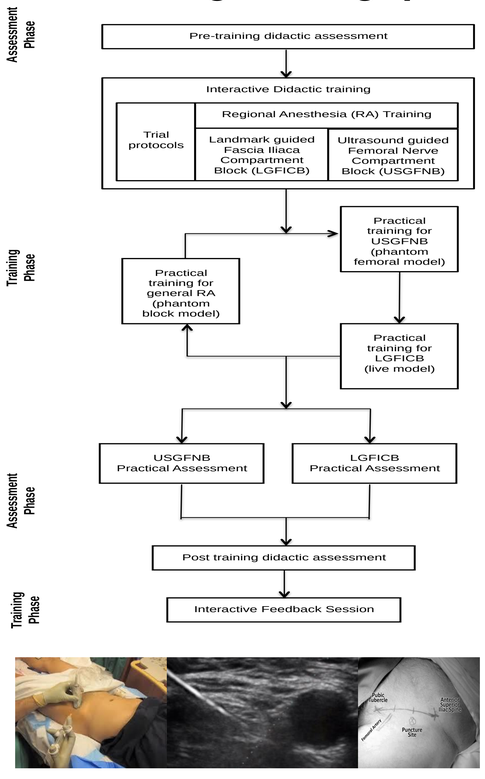
Outcome & Analysis

- Sample size 207 patients (equivalency design) to detect 20% change in the summed pain intensity difference based on numeric rating scale (NRS) assessment performed 10 times over 24-hours of participant follow-up



Focused Volunteer Responder Training

Training Throughput



Cohort Characteristics

Characteristics	n (%) / Median (IQR)
Age (years)	41 (35, 48)
Sex	
Male	2 (16.7%)
Female	10 (83.3%)
Primary healthcare training	
Nurse	6 (50.0%)
Medical Doctor	6 (50.0%)
Duration providing healthcare (years)	11 (10, 21)
Duration as MSF response personnel (years)	5 (3, 9)
Number of MSF missions	4 (4, 7)
Prior clinical use of ultrasound	
No	6 (50.0%)
Yes	6 (50.0%)
Prior clinical use of regional anesthesia	
No	10 (83.3%)
Yes	2 (16.7%)

Training Outcomes

Assessment Type	Pre-training	Post-training	% Change	p
Didactic Exam Score*	79.2 (73.9-84.4)	88.4 (82.3-94.2)	10.4%	<0.001
	Rater 1†	Rater 2†	kappa	-
LGFICB simulation#	15.0 (14.0, 16.0)	15.0 (15.0, 16.0)	0.83	-
USGFNB simulation#	15.0 (14.0, 16.0)	15.5 (14.5,16.0)	0.92	-

	Healthcare Training		
Assessment Type	Nurse	Physician	p
Pre-training didactic exam*	78.7 (74.3-83.1)	79.6 (67.6-91.7)	0.86
Post training didactic exam*	91.7 (85.6-97.8)	85.2 (73.7-96.1)	0.23
LGFICB assessment#			
Rater 1†	14.5 (14.0, 15.0)	14.0 (14.0, 16.0)	0.18
Rater 2†	15.0 (14.0, 16.0)	15.0 (15.0, 16.0)	0.06
USGFNB assessment#			
Rater 1†	15.5 (15.0, 16.0)	14.0 (14.5, 16.0)	0.35
Rater 2†	15.5 (14.0, 16.0)	15.5 (15.0, 16.0)	0.80

* Values represent the percent mean score with associated 95% confidence intervals (95% CI)
# LGFICB abbreviates landmark guided fascia iliaca block, USGFNB abbreviates ultrasound guided femoral nerve block
† Median score with associated interquartile range (IQR), maximum possible score out of sixteen required critical actions

- 12 humanitarian response providers were enrolled and completed training
  - 83.3% female with equal distribution of nurses and medical doctors
  - Low prior exposure to use of RA (16.7%)
- Knowledge scores significantly improved (+delta:10.4%, p<0.001)
- High rates of successful skill performance for both LGFICB & USGFNB with excellent inter-rater agreement.
- No significant difference in knowledge or skills acquisition between nurses and medical doctors

Discussion

- The RAPID study will be the first trial to prospectively enroll patients in the aftermath of a major earthquake to assess whether RA administered by generalists providers, either with or without US-guidance, can reduce suffering from lower limb injuries. The study will be informative on the topic of acute pain management as well as on the broader subject of performing interventional research in the setting of an acute disaster.

- The training evaluation demonstrated attainment of knowledge and technical skill after focused instruction in regional anesthesia techniques, demonstrating feasibility to efficiently training generalist responders to provide RA.

The Author group has no conflicts of interest to disclose
Ethics approval: Médecins Sans Frontières ERB (1524)
Registration: ClinicalTrials.gov (NCT02698228)
Funding: ELHRA, Research for Health in Humanitarian Crises