Multicenter internAtional raNdomized controlled manIkin study on different protocols of CPR (MANI-CPR)

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Background

The focus on the hands-only cardio-pulmonary resuscitation (CPR), meaning continuous chest compressions until the arrival of EMS without interruptions to perform ventilation, has grown a lot in the last years. The reasons for this are that it's more accepted by lay rescuers [1], it's easier to remember and to perform [2], and, above all, because it has been demonstrated that it has the same efficacy than standard CPR at least in the first minutes after an out-of-hospital cardiac arrest (OHCA) [3], which are the minutes in which it is more probably that a lay rescuer can intervene. For these reasons ILCOR 2010 and also 2015 guidelines recommended this technique for untrained bystanders or for bystanders who are unwilling to give rescue breaths [4,5]. ILCOR 2010 and 2015 guidelines have also pointed out that it's not sufficient to perform only a CPR immediately after an OHCA. In fact they have stressed that this CPR must be an high-quality CPR, that is a CPR with compressions of adequate rate (between 100 and 120 per minute) and adequate depth (between 5 and 6 cm), with complete chest recoil between compressions and minimizing interruptions between compressions. This because it has been shown that an high-quality CPR can improve the survival after an OHCA [4,5]. It has also been demonstrated that the quality of hands-only CPR decades after 1 minute [6], and if we think that the mean time intervention of EMS on a cardiac arrest scenario in Europe is about 8 minute [7], it's easy to comprehend that it is very difficult to perform an high-quality CPR with the hands-only technique. It has also been shown that a 10-seconds pause in the hands-only CPR protocol can increase its quality [8], but, at the moment, there is not a shared protocol to recommend to lay rescuers who are unwilling to give rescue breaths, except to perform chest compressions continuously until EMS arrival.

Purpose

The aim of our study is to verify whether the inclusion of breaks of different frequency and duration during the hands-only CPR could increase chest compressions quality during an 8-minutes scenario.

Materials e Methods

The study can involve multiple training center in Italy and in Europe, that organize BLS/AED courses for lay people according to ILCOR 2015 guidelines, with an instructor:attendees:manikin ratio of 1:5:1, maximum 1:6:1, and with 1 minute training per participant with real-time feedback using a Laerdal QCPR or Resusci Anne Wireless Skill Reporter manikin connected with a QCPR software. At the end of each course for each participant will be recorded the performance of 1-min of compression-only CPR on the QCPR/Resusci Anne Wireless Skill Reporter manikin without visual feedback for the attendee. In order to eliminate any bias due to heterogeneity of the individual quality of CPR, will be asked to participate in the study to all those who, at the end of this test, will have done the compressions at a rate between 100 and 120 per minute with a result> = 90%

in the parameters "percentage of compressions with correct depths (between 5 and 6 cm)", "percentage of correctly released compressions", "percentage of compressions with correct hand position". The participants must be lay people between 18 and 80 years old.
Those who agree to participate in signing the informed consent, will be randomized to one of four arms of the study. The arms of the study are the 4 different CPR protocols: 30 compressions and 2 seconds of pause (30c2s), 50 compressions and 5 seconds of pause (50c5s), 100 compressions and a 10 seconds of pause (100c10s) and continuous chest compressions without any pauses (hands-only).
The subjects were asked to carry out an 8-minutes performance following the protocol assigned to them on the Laerdal QCPR or Resusci Anne Wireless Skill Reporter manikin connected to the QCPR software without any type of feedback or help.
At the end, the performance must be saved as: Name_Surname_Age_Sex(M or F)_Height(cm)_Weight(kg)_Protocol(acronym)
In order to ensure the highest possible quality of data and consistency between the different participating centers, the tests should be recorded, including via smartphones, and will be made available to the leader center.
At the leader center will be also be sent the file of the 1-minute performance recorded at the end of course and the file of the 8-minutes performance carried out after the randomization.

The study has been submitted to a regional ethics committee for medical research (IRCCS Policlinico San Matteo, Pavia, Italy) and was considered exempted from evaluation, in accordance to the Italian law, because it's a study on manikins and it don't involve real patients.

End points

The primary endpoint is the difference in the percentage of compressions with correct depth (50-60 mm) among the groups. Secondary endpoints are the differences in the percentage of correctly released compressions, in the percentage of compressions with correct hand position and in the number of compressions per minute.

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