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JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

PÉCSI TUDOMÁNYEGYETEM UNIVERSITY OF PÉCS

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Points: /13

Read the article below, then according to what you have read complete Task Sheet 2.

Randomized Trial of Three Anticonvulsant Medications for Status Epilepticus

Abstract

(1) In a randomized, blinded, adaptive trial, we compared the efficacy and safety of three intravenous anticonvulsive agents — levetiracetam, fosphenytoin, and valproate — in children and adults with convulsive status epilepticus that was unresponsive to treatment with benzodiazepines. The primary outcome was absence of clinically evident seizures and improvement in the level of consciousness by 60 minutes after the start of drug infusion, without additional anticonvulsant medication. The posterior probabilities that each drug was the most or least effective were calculated. Safety outcomes included life-threatening hypotension or cardiac arrhythmia, endotracheal intubation, seizure recurrence, and death.

(2) A total of 384 patients were enrolled and randomly assigned to receive levetiracetam (145 patients), fosphenytoin (118), or valproate (121). Reenrollment of patients with a second episode of status epilepticus accounted for 16 additional instances of randomization. In accordance with a prespecified stopping rule for futility of finding one drug to be superior or inferior, a planned interim analysis led to the trial being stopped. Of the enrolled patients, 10% were determined to have had psychogenic seizures.

(3) The primary outcome of cessation of status epilepticus and improvement in the level of consciousness at 60 minutes occurred in 68 patients assigned to levetiracetam (47%; 95% credible interval, 39 to 55), 53 patients assigned to fosphenytoin (45%; 95% credible interval, 36 to 54), and 56 patients assigned to valproate (46%; 95% credible interval, 38 to 55). The posterior probability that each drug was the most effective was 0.41, 0.24, and 0.35, respectively. Numerically more episodes of hypotension and intubation occurred in the fosphenytoin group and more deaths occurred in the levetiracetam group than in the other groups, but these differences were not significant.

(4) In the context of benzodiazepine-refractory convulsive status epilepticus, the anticonvulsant drugs levetiracetam, fosphenytoin, and valproate each led to seizure cessation and improved alertness by 60 minutes in approximately half the patients, and the three drugs were associated with similar incidences of adverse events.

TASK SHEET 2

1) Match the phrases expressing the message of a given paragraph (A-F) with the appropriate number indicating the paragraph (1 - 4). There are two options that do not match any of the paragraphs.

A	the outcome of the research	
B	background of the research	
C	the method of research	
D	conclusions	
E	the process of including patients in the study	
F	recommendations	

/4 points

2) Choose the best answer (A, B, C, or D) in each question according to what you have read by putting a cross in the box of your choice.

Q01

	A	Researchers studied the efficacy of blind children in adapting to treatment options.
	B	The efficacy of three tablets administered to children and adults were studied.
	C	The efficacy and safety of three anticonvulsive agents were compared.
	D	Convulsive status epilepticus was unresponsive to three anticonvulsive agents.

Q02

	A	Benzodiazepines are always effective in treating children with convulsive status epilepticus.
	B	Levetiracetam, phosphenytoin and valproate are intravenous anticonvulsive agents.
	C	Convulsive status epilecticus is always unresponsive to benzodiazepines in adults.
	D	Benzodiazepines are ineffective in treating patients with convulsive status epilepticus.

Q03

	A	Seizures occur when improvement in the level of consciousness becomes evident.
	B	Life threatening hypotension was not regarded as a safety outcome.
	C	Cardiac arrhythmia develops when clinically evident seizures are absent.
	D	The researchers calculated the probability of each drug being the best or worst.

Q04

	A	16 patients were enrolled only once.
	B	121 patients received fosphenytoin or valporate.
	C	Altogether 384 patients were enrolled .
	D	All the patients were reenrolled.

Q05

	A	The trial was regarded as futile.
	B	In accordance with rules specified previously the trial was not stopped.
	C	Psychogenic seizure occurred in 10% of all patients.
	D	The rank order of the three anticonvulsive agents was established.

Q06

	A	Cessation of status epilepticus occurred in 47% of patients administered with levetiracetam.
	B	Status epilepticus in 45% of patients assigned to fosphenytoin did not improve.
	C	In 46% of patients assigned to valproate no improvement in the level of consciousness occurred.
	D	No improvement of status epilepticus occurred in 47% of patients taking levetiracetam.

Q07

	A	Significant differences were found in the efficacy of the three drugs.
	B	No significant differences were found in the efficacy of the three drugs.
	C	The incidence of hypotension was higher in the levetiracetam group than in other groups.
	D	The incidence of death was the highest in the levetiracetam group.

Q08

	A	More than 50 percent of all patients with status epilepticus experienced improvement as a result of receiving one of the three intravenous anticonvulsive agents.
	B	In less than 50 percent of all cases one of the three intravenous anticonvulsive agents proved effective in treating status epilepticus.
	C	In exactly 50 percent of all cases one of the three intravenous anticonvulsive agents proved effective in treating status epilepticus.
	D	Neither of the three anticonvulsive agents proved efficient in treating status epilepticus.

Q09

	A	The incidence of adverse events is similar in the three drugs trialled in the study.
	B	Not all the three drugs produced cessation of status epilepticus.
	C	Only one of the three anticonvulsive drugs caused improvement in status epilepticus.
	D	Status epilepticus cannot be treated successfully with either of the three drugs trialled.

Points: /13

1) Match the phrases expressing the message of a given paragraph (A-F) with the appropriate number indicating the paragraph (1 - 4). There are two options that do not match any of the paragraphs.

A	the outcome of the research	3
B	background of the research	-
C	the method of research	1
D	conclusions	4
E	the process of including patients in the study	2
F	recommendations	-

/4 points

2) Choose the best answer (A, B, C, or D) in each question according to what you have read by putting a cross in the box of your choice.

Q01

	A	Researchers studied the efficacy of blind children in adapting to treatment options.
	B	The efficacy of three tablets administered to children and adults were studied.
x	C	The efficacy and safety of three anticonvulsive agents were compared.
	D	Convulsive status epilepticus was unresponsive to three anticonvulsive agents.

Q02

	A	Benzodiazepines are always effective in treating children with convulsive status epilepticus.
x	B	Levetiracetam, phosphenytoin and valproate are intravenous anticonvulsive agents.
	C	Convulsive status epilecticus is always unresponsive to benzodiazepines in adults.
	D	Benzodiazepines are ineffective in treating patients with convulsive status epilepticus.

Q03

	A	Seizures occur when improvement in the level of consciousness becomes evident.
	B	Life threatening hypotension was not regarded as a safety outcome.
	C	Cardiac arrhythmia develops when clinically evident seizures are absent.
x	D	The researchers calculated the probability of each drug being the best or worst.

Q04

	A	16 patients were enrolled only once.
	B	121 patients received fosphenytoin or valporate.
x	C	Altogether 384 patients were enrolled.
	D	All the patients were reenrolled.

Q05

	A	The trial was regarded as futile.
	B	In accordance with rules specified previously the trial was not stopped.
x	C	Psychogenic seizure occurred in 10% of all patients.
	D	The rank order of the three anticonvulsive agents was established.

Q06

	A	Cessation of status epilepticus occurred in 47% of patients administered with levetiracetam.
x	A	(see above)
	B	Status epilepticus in 45% of patients assigned to fosphenytoin did not improve.
	C	In 46% of patients assigned to valproate no improvement in the level of consciousness occurred.
	D	No improvement of status epilepticus occurred in 47% of patients taking levetiracetam.

Q07

	A	Significant differences were found in the efficacy of the three drugs.
	B	No significant differences were found in the efficacy of the three drugs.
	C	The incidence of hypotension was higher in the levetiracetam group than in other groups.
x	D	The incidence of death was the highest in the levetiracetam group.

Q08

	A	More than 50 percent of all patients with status epilepticus experienced improvement as a result of receiving one of the three intravenous anticonvulsive agents.
x	B	In less than 50 percent of all cases one of the three intravenous anticonvulsive agents proved effective in treating status epilepticus.
	C	In exactly 50 percent of all cases one of the three intravenous anticonvulsive agents proved effective in treating status epilepticus.
	D	Neither of the three anticonvulsive agents proved efficient in treating status epilepticus.

Q09

x	A	The incidence of adverse events is similar in the three drugs trialled in the study.
	B	Not all the three drugs produced cessation of status epilepticus.
	C	Only one of the three anticonvulsive drugs caused improvement in status epilepticus.
	D	Status epilepticus cannot be treated successfully with either of the three drugs trialled.

/9 points