e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2022; 14(3); 432-439

Original Research Article

Efficacy of Epidural Infusion in Pain Relief of 0.0625% Bupivacaine with 1µGM/CC Fentanyl for Postoperative Analgesia After Major Abdominal Surgeries Using Elastomeric Infusion Pump (Infusor Baxter Health Care USA) or Electronic (EMCO) Infusion Pump

Ankita Singh

Junior Resident, Department of Anesthesia, LTMMC Sion Hospital, Mumbai, Maharashtra, India

Received: 23-01-2022 / Revised: 26-02-2022 / Accepted: 20-03-2022
Corresponding author: Dr. Ankita Singh
Conflict of interest: Nil

Abstract

Aim: To evaluate the use of electronic and elastomeric infusion pumps for administration of local anesthetics for post-operative analgesia in the major abdominal surgeries with regard to – Pain relief: static & dynamic.

Material & Methods: After institutional ethics committee approval, a prospective, observational, comparative study was carried out in 80 patients of either sex between ages of 18 to 65 years undergoing major abdominal surgery. The patients were into two groups of 40 patients each, elastomeric pumps (Group A) or electronic pumps (group B).

Results: The age of the patients in the study ranged from 20.00 – 64.00 years. Baseline Mean VAS at rest was 6.95 in Elastomeric group and 7.05 in electronic pump. The median in both the groups was 7 with an IQR of 2.00. Thus, the baseline was comparable, and the difference was not significant. (P = 0.746) Mean VAS at dynamic state that is at mobility was 8.00 in Elastomeric group and 8.33 in electronic group. At the end of 24 hrs, Mean VAS was reduced significantly from baseline to 1.18 in Elastomeric group and 1.43 in electronic group. Median and IQR was 1 and 2 in both the groups. This difference was statistically insignificant. (P = 0.330).

Conclusion: Post-operative pain has many deleterious effects. Epidural analgesia is the most effective method to provide sustained pain relief. Baxter Elastomeric Pumps are non-electronic medication pumps which are said to be equally efficacious to electronic pump with respect to good pain relief.

Keywords: epidural infusion, pain relief, elastomeric infusion pump, electronic (EMCO) infusion pump

Introduction

Effective postoperative pain control is an essential component of care of the surgical patient. Surgical procedures are characterized by incisional damage to skin and various tissues, application of thermal and chemical stimuli to wound and often prolonged traction, dissection and manipulation of somatic and visceral

structures. Nociceptive pain is often regarded as the key feature of acute postoperative pain. This is caused by release of inflammatory mediators which activate peripheral nociceptors which initiate transduction and transmission of nociceptive information to CNS. There is also release of substance P and calcitonin which produce vasodilatation and extravasation. [1-4] Besides this, neuropathic pain mechanisms may contribute to the pain occurring during postoperative period.

Postoperative pain plays a major role in the recovery following surgery especially in major abdominal surgeries. It causes tachycardia, hypertension and may lead to myocardial ischemia in a vulnerable subject. Pain prevents deep breathing, causes splinting of diaphragm and promotes basal atelectasis leading to postoperative pulmonary complications. It prevents early mobilization of patients and contributes to deep vein thrombosis. In addition, uncontrolled postoperative pain can produce a neuroendocrine stress response which in turn causes release of catabolic hormones like catecholamine, cortisol, glucagon, and renin [5-7].

There are many methods available to provide analgesia, including systemic analgesics (i.e. Opioid and non-opioid) and regional (i.e., neuraxial and peripheral) analgesic technique, but epidural analgesia using local anesthetics forms the gold standard for abdominal, thoracic and lower extremity surgeries.

In this study, we aim to evaluate the use of electronic and elastomeric infusion pumps for administration of local anesthetics for post-operative analgesia in the major abdominal surgeries with regard to – Pain relief: static & dynamic.

Material & Methods:

After institutional ethics committee approval, a prospective, observational, comparative study was carried out in 80 patients of either sex between ages of 18 to 65 years undergoing major abdominal surgery. The patients were into two groups of 40 patients each, elastomeric pumps (Group A) or electronic pumps (group B).

Place and area of study: general surgery and urology operation theatres of LTMGH

Inclusion criteria:

1. Age more than 18 years
2. Elective major abdominal surgical patients requiring epidural blockade for postoperative analgesia
3. Patient willing to consent

Exclusion criteria:

1. Patients with infection at the site of catheter insertion
2. Patients with coagulopathy, intra-cranial hypertension, severe hypovolemia
3. Patients for emergency surgery
4. Obstetric patients and lactating mothers
5. Any known allergy to the local anesthetic drug used

Methodology

80 adult patients undergoing elective major abdominal surgeries after written informed consent were included in the study. A thorough preoperative checkup was carried out which included physical examination and investigations according to institutional protocol.

After checking for starvation, consent and fitness, an intravenous line was established, and IV fluids were started. Standard monitoring which includes ECG, blood pressure, pulse oximeter was initiated. Patients were explained the procedure, given position, back was scrubbed, painted & draped. An epidural catheter of 18G was inserted in the lumbar or lower thoracic area depending upon the surgical requirement. Standard protocol for general anesthesia with endotracheal intubation was followed.

Epidural analgesia was started before surgery using 0.125%bupivacaine 8cc by

an anesthesiologist conducting the case, subsequent doses was given every 2 hrs or when patient‘s physiologic parameters mandated it. The conduct of anesthesia and monitoring was as per standard protocol.

Patient was reversed and extubated on return of consciousness after meeting extubation criteria or mechanically ventilated.

After emergence from anesthesia patient was shifted to post-operative recovery room. Pain was assessed by recovery room anesthetist and the epidural infusion was started. Epidural infusion used was local anesthetic solution containing 0.0625 % bupivacaine +1 mcg /cc fentanyl. The patients were divided into two groups:

Group A: in which epidural analgesia was delivered using elastomeric pump. 250 cc of 0.0625% bupivacaine + 1mcg/cc fentanyl was aspirated into the Infusor. The dead space volume of the Infusor tubing is 3 cc which was considered at the time of calculating volume delivered to the patient.

Group B: in which epidural analgesia was delivered using an electronic pump. 50 cc of 0.0625% bupivacaine + 1mcg/cc fentanyl (i.e.1cc =50 μ) total 51 cc; was aspirated in a 60 cc syringe. A high-pressure line (PMO line) with capacity 0.90cc was connected to the syringe and primed with the solution.

In both the groups the drug was aspirated under aseptic precautions and the pumps was kept at the level of the patient‘s bed.

The flow was adjusted according to the VAS score on shifting.

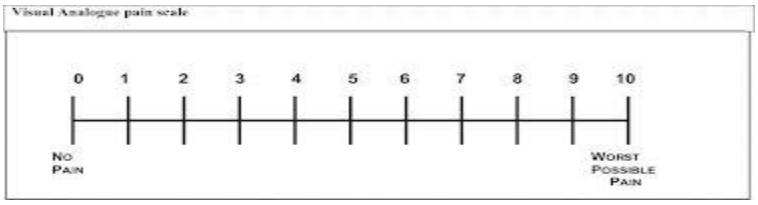
If VAS score was >3 but ≤ 5 then epidural infusion was started at the rate 5 ml/hr. in both the groups. If VAS Score is ≥ 6 but <8 then infusion rate was started at 7 ml/hr. in both the groups.

If VAS score is ≥ 8 then infusion was started at 12 ml/hr. in both groups.

After initiation of infusion, assessment of the following parameters was carried out every 10 minutes till 30 minutes. Subsequently, every 30 minutes till 90 minutes and thereafter every hourly till a period of 24 hours and whenever patient complained of pain. The aim was to keep VAS < 4.

Prefilled 50 cc syringes were kept ready for electronic pumps and changed as soon as the contents of the previous syringe were exhausted. The elastomeric pump was 40 inspected from time to time for continued deflation of the balloon with time. A count was kept of the total number of syringe refills.

Pain was assessed by **visual analogue score** (0-no pain, 10-worse pain) at rest and at dynamic states such as coughing or limb movements.



In our study, the data was analyzed for normalcy of distribution and was expressed as mean and standard deviation. Categorical data was analyzed by Chi-square test, parametric data was analyzed by unpaired t- test. Non-parametric data like VAS score at rest and dynamic, quality of sensory block, modified bromage score and satisfaction score was expressed as median and Inter-Quartile Range (IQR) and tested with Mann-Whitney u test. P- value of ≤ 0.05 was considered as significant.

Results:

The present study is a prospective, observational study involving two groups viz, elastomeric pump group and

electronic pump group having 40 patients each.

The age of the patients in the study ranged from 20.00 – 64.00 years. Table 1 reveal that the average age was 43.30 years in Elastomeric group, which was comparable with 45.43 years in Electronic group and the difference was not significant.(P = 0.424). 47.5% of the patients were male in Elastomeric group and 65% in Electronic group and difference was not significant. (P = 0.115). Hence, both groups were comparable demographically.

Table 2 shows types of surgeries and thus both the groups had major abdominal surgeries having similar degree of surgical invasiveness.

As per table 3 and figure 9c baseline Mean VAS at rest was 6.95 in Elastomeric group and 7.05 in electronic pump. The median in both the groups was 7 with an IQR of 2.00. Thus, the baseline was comparable, and the difference was not significant. (P = 0.746) A VAS score of less than 4 was considered as adequate analgesia. At the end of 3 hrs Mean VAS was reduced to 3.70 in Elastomeric group and 3.85 in electronic group. The median and IQR was 4 and 2 in both the groups, with difference being statistically insignificant. (P = 0.565). At the end of 10 hrs both groups had lower Mean VAS of 1.93, median of 1 and IQR of 2 in Elastomeric group and Mean VAS of 2.10, Median of 2 and IQR was 2in Electronic group, the difference was statistically insignificant. At the end of 24 hrs, Mean VAS was significantly reduced from baseline to 0.75 with Median of 0 and IQR of 1 in Elastomeric group and Mean VAS of 0.88, Median and IQR of 1 in electronic group, and the difference between the groups was statistically insignificant. (P = 0.516). In table 4, at each time duration, the dynamic VAS was higher than the VAS at rest as expected.

A VAS score of less than 4 was considered as adequate analgesia. Table no.4 shows that baseline Mean VAS at dynamic state that is at mobility was 8.00 in Elastomeric group and 8.33 in Electronic group. The Median and IQR was 8 and 2 in Elastomeric group and 8 and 1 in Electronic group. The baseline value of the two groups was comparable and difference was not significant. (P = 0.268). At the end of 3 hrs, Mean VAS at dynamic was reduced to 4.70 in Elastomeric group and 4.98 in electronic group. Median and IQR was 5 and 2 in both the groups. The difference was not significant. (P = 0.310). At the end of 10 hrs Mean VAS score was 2.90 with Median and IQR of 2 and 3.5 in Elastomeric group and Mean vas was 3.25 with Median and IQR of 3 and 2.5 in electronic group, but the difference was statistically insignificant. (P = 0.359). At the end of 24 hrs, Mean VAS was reduced significantly from baseline to 1.18 in Elastomeric group and 1.43 in electronic group. Median and IQR was 1 and 2 in both the groups. This difference was statistically insignificant. (P = 0.330).

Table 1: Demographical data

PARAMETERS	ELASTOMERIC PUMP	ELECTRONIC PUMP
No. of Cases	**40**	**40**
#Age(yrs.) Mean SD Range	43.30 12.30 20.00 - 64.00 yrs.	45.43 11.35 21.00 - 64.00 yrs.
@Sex (%) Male Female	19(47.5) 21(52.5)	26(65.0) 14(35.0)

#by unpaired T test Not Significant (P = 0.424)
@ By Chi Square test Not Significant (P = 0.115)

Table 2: Types of surgeries

SURGERY	ELASTOMERIC PUMP	ELECTRONIC PUMP
GI surgeries	28	33
Urosurgeries	5	2
Gynecological	7	4
Incisional hernia repair	0	1

Table 3: Comparison of vas score at rest

VAS at Rest		ELASTOMERIC PUMP			ELECTRONIC PUMP			P Value	
Mean	Std. Dev.	Median		IQR	Mean		Std. Dev.	Median	IQR
0 min	6.95	1.58	7.00	2.00	7.05	1.36	7.00	2.00	0.746
10 min	6.98	1.54	7.00	2.00	7.20	1.36	7.00	2.00	0.481
20 min	6.53	1.57	6.00	3.00	6.75	1.53	7.00	2.50	0.524
30mins	5.85	1.69	6.00	2.50	5.83	1.41	6.00	2.00	0.860
60 mins	5.38	1.60	5.00	3.00	5.30	1.32	5.00	1.50	0.902
90 mins	4.65	1.79	5.00	2.50	4.50	1.66	5.00	3.00	0.836
2hrs	4.03	1.72	4.00	3.00	4.15	1.41	4.00	2.00	0.695
3hrs	3.70	1.60	4.00	2.00	3.85	1.51	4.00	2.00	0.565
4hrs	3.25	1.69	3.00	2.00	3.20	1.57	3.00	2.00	0.992
5hrs	2.93	1.85	3.00	2.50	2.93	1.46	3.00	2.00	0.739
6hrs	2.58	1.66	2.00	2.50	2.73	1.58	2.00	2.00	0.612
7hrs	2.35	1.59	2.00	2.00	2.58	1.68	2.00	3.00	0.556
8hrs	2.35	1.67	2.00	3.00	2.50	1.88	2.00	2.50	0.788
9hrs	2.10	1.58	2.00	2.50	2.55	1.97	2.00	3.00	0.355
10hrs	1.93	1.62	1.00	2.00	2.10	1.57	2.00	2.00	0.476
11hrs	1.98	1.78	1.00	3.00	1.85	1.67	1.00	1.50	0.913
12hrs	2.33	1.85	1.50	3.00	1.95	1.58	1.50	2.00	0.418
13hrs	2.43	2.10	2.00	3.00	1.93	1.76	1.00	2.00	0.303
14hrs	2.58	2.09	2.00	2.50	2.23	1.75	2.00	2.00	0.510
15hrs	2.40	1.65	2.00	2.00	2.00	1.36	2.00	2.00	0.279
16hrs	2.20	1.52	2.00	2.50	2.03	1.48	2.00	2.00	0.653
17hrs	1.90	1.19	1.50	1.50	2.18	1.63	2.00	2.00	0.658
18hrs	1.90	1.55	2.00	2.00	2.05	1.77	1.00	2.00	0.867
19hrs	1.88	1.57	1.00	2.50	2.20	1.90	2.00	3.00	0.547
20hrs	1.75	1.66	1.00	3.00	2.08	1.99	2.00	4.00	0.574
21hrs	1.50	1.36	1.00	1.00	1.85	1.92	2.00	2.50	0.549
22hrs	1.20	1.14	1.00	2.00	1.40	1.24	1.00	1.00	0.416
23hrs	1.00	1.22	1.00	1.00	1.23	1.27	1.00	2.00	0.311
24hrs	0.75	1.10	0.00	1.00	0.88	1.16	1.00	1.00	0.516

Table 4: Comparison of dynamic vas score

Dynamic VAS Score	ELASTOMERIC PUMP				ELECTRONIC PUMP				P Value
	Mean	Std. Dev.	Median	IQR	Mean	Std. Dev.	Median	IQR	
0 min	8.00	1.32	8.00	2.00	8.33	1.02	8.00	1.00	0.268
10 mins	7.93	1.38	8.00	2.00	8.15	1.23	8.00	1.00	0.369
20 mins	7.40	1.50	7.00	1.50	7.70	1.29	8.00	1.50	0.336
30mins	7.03	1.53	7.00	2.00	6.98	1.42	7.00	2.00	0.806
60 mins	6.38	1.37	6.00	1.00	6.53	0.99	7.00	1.00	0.628
90 mins	5.78	1.54	6.00	2.50	6.00	1.06	6.00	2.00	0.520
2hrs	5.30	1.79	5.00	2.50	5.40	1.37	5.50	1.50	0.600
3hrs	4.70	1.70	5.00	2.00	4.98	1.54	5.00	2.00	0.310
4hrs	4.30	1.70	4.00	2.00	4.40	1.50	5.00	2.50	0.659
5hrs	4.08	1.83	4.00	2.00	4.23	1.51	4.00	2.50	0.521
6hrs	3.70	1.84	4.00	2.00	4.08	1.58	4.00	2.00	0.228
7hrs	3.30	1.70	3.00	2.00	3.85	1.48	4.00	2.00	0.061
8hrs	3.33	1.79	3.00	3.00	3.73	1.85	3.00	3.00	0.342
9hrs	3.20	1.90	3.00	3.00	3.55	1.93	3.00	3.00	0.390
10hrs	2.90	1.79	2.00	3.50	3.25	1.86	3.00	2.50	0.359
11hrs	2.83	1.89	2.00	3.00	2.83	1.69	3.00	3.00	0.844
12hrs	2.98	2.04	2.00	4.00	2.63	1.56	2.00	1.00	0.874
13hrs	3.15	2.05	2.00	3.00	3.08	1.94	2.50	2.50	0.992
14hrs	3.30	2.13	3.00	3.00	3.30	1.77	3.00	2.00	0.775
15hrs	3.20	1.84	3.00	2.00	2.93	1.61	2.50	2.00	0.487
16hrs	3.15	1.78	3.00	2.00	3.25	1.68	3.00	2.50	0.887
17hrs	2.85	1.56	2.00	2.00	3.08	1.82	2.50	2.00	0.689
18hrs	2.80	1.80	2.00	3.00	3.13	1.86	3.00	2.00	0.454
19hrs	2.73	1.74	2.00	3.00	3.15	2.13	2.00	2.00	0.398
20hrs	2.63	1.75	2.00	3.00	3.28	2.09	3.00	4.00	0.165
21hrs	2.38	1.58	2.00	2.00	2.78	1.76	2.00	1.50	0.236
22hrs	2.08	1.33	2.00	1.50	2.35	1.33	2.00	1.50	0.225

By Mann-Whitney u test

Discussion:

Though pain has a protective function, uncontrolled pain in the postoperative period not only increases the agony of the patient but also precipitates a neuro-endocrine stress response which in turn causes release of catabolic stress hormones like catecholamines, cortisol, glucagon, renin etc. This leads to

(1) Negative nitrogen balance and protein catabolism.

(2) Stress contributes to postoperative hypercoagulability, immunosupression and hyperglycemia which leads to poor wound healing.

(3) Increased myocardial oxygen consumption leading to myocardial ischemia.

(4) Pain results in voluntary decrease in the movement of the muscles of the abdomen and the thorax and splinting of diaphragm causing decreased lung volumes and impaired cough leading to stagnation of secretions and atelectasis.

(5) Paralytic ileus.

Thus, optimizing treatment of acute postoperative pain can improve morbidity and health related quality of life. Epidural analgesia addresses most of these problems. It reduces the incidence of myocardial ischemia, improves respiratory function, and allows early mobilization of patient and return of bowel function and shorter hospital stay. Local anesthetics along with lipophilic opioid analgesics have become a popular choice these days.

Moderate to severe postoperative pain commonly occurs following laparotomy and inadequate analgesia may aggravate postoperative morbidity. Conventional intermittent IM opioid injection fails to provide satisfactory analgesia in the majority of cases [8-10]. Analgesic techniques like epidural analgesia and PCA are more effective than IM opioid and are commonly employed [11-12].

Our study showed that mean baseline VAS at mobility/coughing was 8.00 in Elastomeric group and 8.33 in electronic group. Median was 8 in both groups at baseline. Both groups were comparable, and difference was not significant. ($P = 0.268$) At each time duration, the dynamic VAS was higher than the VAS at rest as expected. A VAS score of less than 4 was considered as adequate analgesia. At the end of 24 hrs, mean VAS was reduced significantly from baseline to 1.18 in Elastomeric group and 1.43 in electronic group. Though the difference between the two groups was statistically insignificant. ($P = 0.330$) Throughout the study period the dynamic mean VAS score was comparable in both the groups.

Maria cristina et al [13] in 2011 compared continuous epidural catheter infusion of local anesthetic and opioid and continuous wound catheter infusion of local anesthetic for postoperative analgesia in 39 patients undergoing elective laparotomy. Group 1 (G1) received postoperative patient-controlled epidural analgesia (PCEA) with continuous infusion of ropivacaine and fentanyl using elastomeric pump with patient control module while Group 2 (G2) received postoperative patient-controlled continuous wound catheter infusion of ropivacaine. They showed that there was significant reduction in pain at rest and with movement in group 1 compared to group 2 patients. ($P < 0.05$)

Similar study was done by Rachid cherkab et al [14] in 2014. They did study of postoperative epidural analgesia in thoracic surgery using continuous administration by electric push-syringe versus elastomeric diffuser in 70 patients. In their study VAS score showed no significant difference between the two groups during the 96 hours after the surgery, both at rest or during the cough. All the patients in the two groups had a VAS score of less than three at rest. At the moment of cough/mobility, only 11.3% had a score greater than three in the electronic group versus 14.3% in the elastomeric group ($P=0.64$).

Capdevila, Xavier et al [15] in 2001 compared Electronic versus Elastomeric pump in controlled perineural analgesia in 76 patients. The median values of these VAS scores were low (i.e., from 6 mm to 13 mm and from 21 mm to 25 mm, respectively, for minimal and maximal VAS values) without any difference among groups.

Conclusion:

Post-operative pain has many deleterious effects. Epidural analgesia is the most effective method to provide sustained pain relief. Baxter Elastomeric Pumps are non-electronic medication pumps which are said to be equally efficacious to electronic pump with respect to good pain relief.

References:

1. Julius D, Basbaum AI, Molecular mechanisms of nociception: Nature 413:203, 2001.
2. Kehlet H: Modification of responses to surgery by neural blockade, In Cousins MJ, Bridenbaugh PO (eds): Neural blockade in clinical anaesthesia and management of pain, 3rd ed. Philadelphia, 1998, Lippincott-Raven, p 129.
3. Wu CL, Fleisher LA: Outcomes research in regional anaesthesia and analgesia. AnesthAnalg91:1232, 2000.
4. Wheatley R, Schug S, Watson D. Safety and efficacy of postoperative epidural analgesia. Br J Anaesth 2001;87:47-61.
5. Liu SS, Bernards CM. Exploring the epidural trail: Reg Anesth Pain Med27:122, 2002.
6. Virmani R, Ghai A, Singh DK, A study to compare continuous epidural infusion and intermittent bolus of bupivacaine for postoperative analgesia following renal surgery. SAJAA 2008; 14(4): 19-22.
7. Davies NJ, Cashman JN. Lee‘s Synopsis of Anaesthesia, 13th edition. Oxford: Butterworth Heinemann; 2006.
8. Kuhn S, Cooke K, Collins M, Jones JM. Perception of pain relief after surgery. Btit Med J 1990; 300:1687-1690.
9. Austin KL, Stapleton JV, Mather LE. Multiple intramuscular injections: A major source of variability in analgesic response to meperidine. Pain 1980; 8:47-62.
10. Tsui SL, Chan CS, Chan ASH, Wong SJ, Lam CS, Jones RDM. Postoperative analgesia for oesophagectomy: a comparison of three analgesic regimens. Anaesth Intensive Care 1991; 19:329- 337.
11. George KA, Wright PMC, Chisakuta A. Continuous thoracic epidural fentanyl for post-thoracotomy pain relief: with or without bupivacaine? Anaesthesia 1991; 46:732-736.
12. Eisenach JC, Grice SC, Dewan DM. Patient-controlled analgesia following caesarean section: a comparison with epidural and intramuscular narcotics. Anesthesiology 1988; 68:444-448.
13. Maria Cristina Simões de Almeida, Giovani de Figueiredo Locks, Horácio Pereira Gomes, Guilherme Muriano Brunharo, Ana Laura Colle Kauling, Postoperative Analgesia: Comparing Continuous Epidural Catheter Infusion of Local Anesthetic and Opioid and Continuous Wound Catheter Infusion of Local Anesthetic. Rev Bras Anestesiol 2011; 61(3): 293-303.
14. Rachid Cherkab, Mohamed Lazraq, Zakaria Elhafid, Wafaa Haddad, Chafik Elkettani, Lahoucine Barrou1, Souheil Boubia and Mohamed Ridai. Postoperative epidural analgesia in thoracic surgery: continuous administration by electric push-syringe diffusion versus elastomeric diffuser. Chronicles of Anesthesiology and Perioperative Medicine 2014: ISSN 2058-7791.58
15. Xavier Capdevila, Philippe Macaire, Philippe Aknin, Christophe Dadure, Nathalie Bernard, and Sandrine Lopez, Patient-controlled perineural analgesia after ambulatory orthopaedic surgery: A comparison of Electronic versus Elastomeric pumps. Anesth Analg 2003; 96:414–7.
16. Manfred, D. May There Exist Healthy Diseases?. Journal of Medical Research and Health Sciences, 2022:5(3), 1801–1803.