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# ANNALS OF PALLIATIVE MEDICINE

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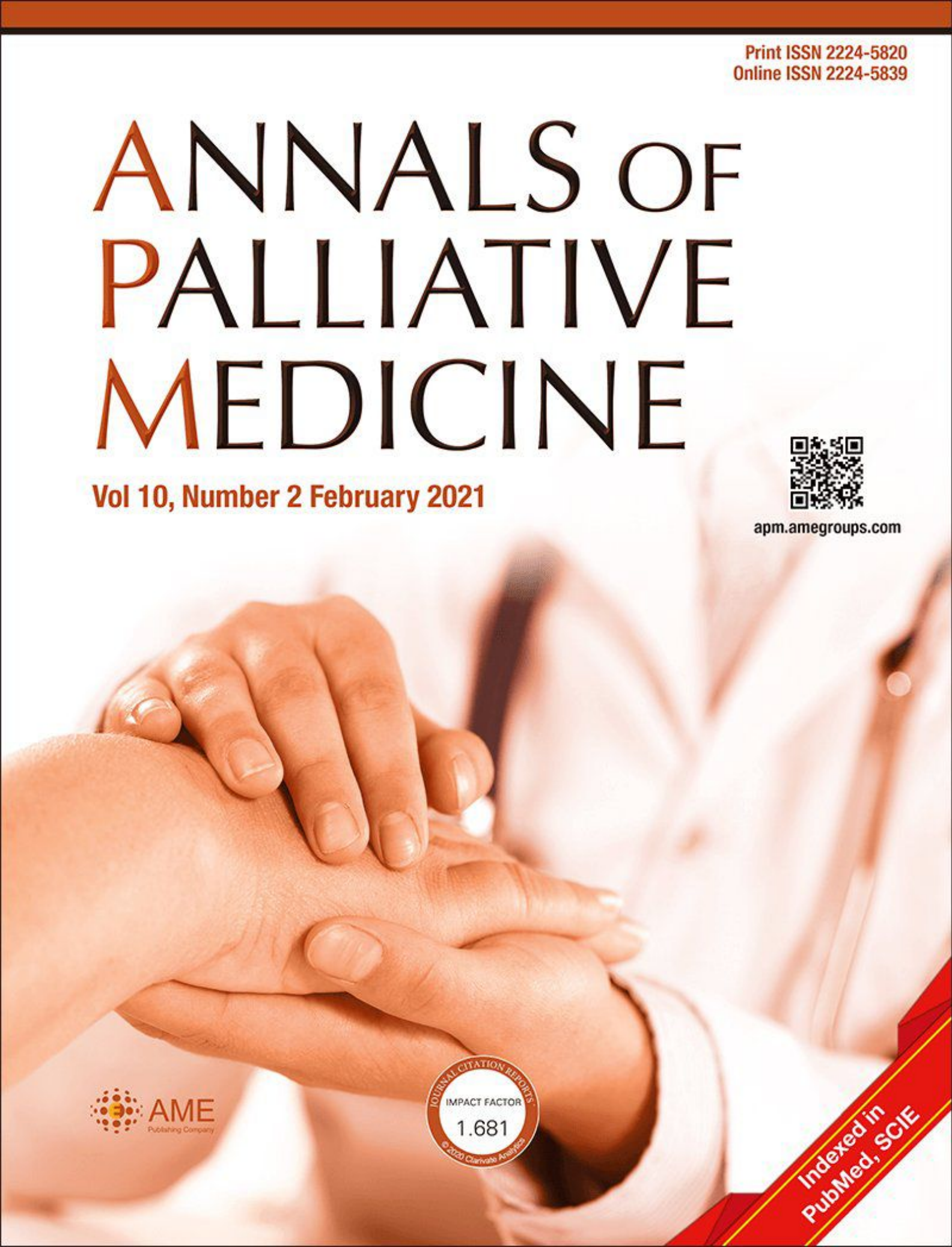

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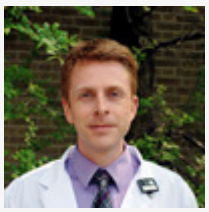

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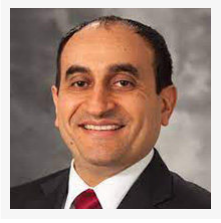

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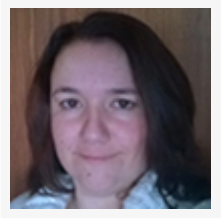

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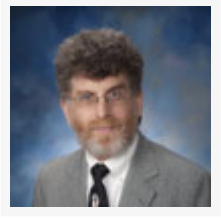

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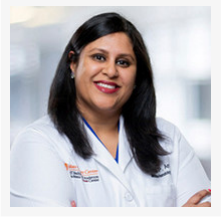

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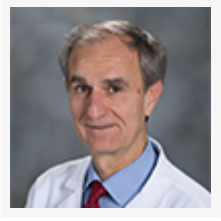

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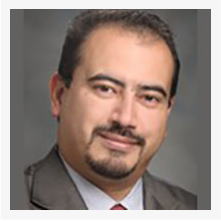

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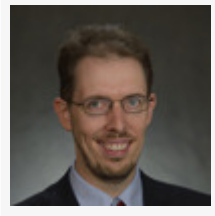

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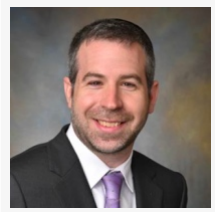

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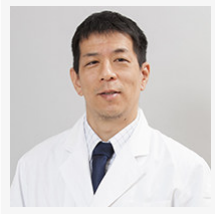

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# Vol 10, No 2 (February 2021): Annals of Palliative Medicine

## Editorial Commentary

### The value of triggered geriatrics and palliative care consults in hospital medicine during the COVID-19 response

Elizabeth H. Prsic, Jennifer A. Ouellet, James M. Lai

PDF Pages: 970-972 Full Text (1055) COI Form Open Access Get Permission

## Original Article

### Randomized research on the mechanism of local oxygen therapy promoting wound healing of diabetic foot based on RNA-seq technology

Shuo Wang, Li-Feng Pan, Lei Gao, Xin-Yuan Qin, Jiang-Ning Wang

PDF Pages: 973-983 Full Text (1519) Reporting Checklist Data Sharing Statement Peer Review File COI Form Open Access Get Permission

### Efficacy of unilateral hemilaminectomy for intraspinal tumor resection: a systematic review and meta-analysis

Deqiang Lei, Yinchun Zhou, Dongxiao Yao, Fangcheng Zhang, Xuan Wang, Xiaobing Jiang, Nanxiang Xiong, Hongyang Zhao

PDF Pages: 984-999 Full Text (834) Reporting Checklist COI Form Open Access Get Permission

### A meta-analysis of efficacy and safety of PDE5 inhibitors in the treatment of ureteral stent-related symptoms

Dongxu Zhang, Kai Sun, Tianqi Wang, Gang Wu, Jipeng Wang, Jitao Wu, Jian Ma, Yuanshan Cui

PDF Pages: 1000-1011 Full Text (794) Reporting Checklist Peer Review File COI Form Open Access Get Permission

### Lactate level and unplanned readmission to the surgical intensive care unit: a retrospective cohort study

Tak Kyu Oh, Chami Im, In-Ae Song

PDF Pages: 1012-1020 Full Text (677) Reporting Checklist Data Sharing Statement COI Form Open Access Get Permission

## Application of leukocyte subsets and sperm DNA fragment rate in infertile men with asymptomatic infection of genital tract

Kang-Sheng Liu, Xiao-Dong Mao, Feng Pan, Ya-Jun Chen

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## Relationship between insulin-sensitive obesity and retinal microvascular abnormalities

Wei Lin, Huiying Rao, Huibin Huang, Jin Yao, Jixing Liang, Liantao Li, Junping Wen, Gang Chen

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## Tracheal stent placement provides opportunity for subsequent anti-cancer therapy for cancer patients with malignant respiratory complications

Gang Ma, Rong Yang, Baochun Gu, Daofeng Wang, Wei Liao, Xinrong He

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## The effects of endoplasmic reticulum stress on the expression of exosomes in ventilator-induced lung injury

Liyun Piao, Hyun-Jun Park, Eun-Hye Seo, Tae-Won Kim, Je-Kyoun Shin, Seong-Hyop Kim

PDF Pages: 1050-1058 Full Text (884) Reporting Checklist Data Sharing Statement COI Form

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## DNA methylation changes in the hippocampus of learning and memory disorder offspring rats of lead exposure during pregnant and lactation period

Tao Hong, Shou-Ming Li, Bo Jia, Yun Huang, Kun Shu, Ke-Wang Yuan, Lai Chen, Long-Xue Li, Li Liu, Zhi-Yong Liu

PDF Pages: 1059-1069 Full Text (931) Reporting Checklist Data Sharing Statement COI Form

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## Effect of combined treatment with pulsed electromagnetic field stimulation and sclerostin monoclonal antibody on changes in bone metabolism and pedicle screw augmentation in rabbits with ovariectomy-induced osteoporosis

Guang Qian, Minghai Wang, Youhai Dong, Yang Hong, Yueming Yu, Jiong Mei

PDF Pages: 1070-1078 Full Text (878) Reporting Checklist Data Sharing Statement COI Form

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## Changes in alkaline phosphatase, calcium, C-reactive protein, D-dimer, phosphorus and hemoglobin in elderly osteoporotic hip fracture patients

Zhineng Chen, Lili Xie, Jie Xu, Xiaofang Lin, Juncai Ye, Rongxue Shao, Xinmiao Yao

PDF Pages: 1079-1088 Full Text (966) Reporting Checklist Data Sharing Statement COI Form

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## Validation of the protective effects of *Lonicera japonica* polysaccharide on lipopolysaccharide-induced learning and memory impairments via regulation of autophagy based on network pharmacology

Jiandong Wang, Ping Liu, Xiaobo Huang, Xiling Wu

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## Prevalence of resuscitation in cancer patients at the end of life—a population-based observational study from Germany

Burkhard Dasch, Philipp Lenz, Peter K. Zahn

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## Multi-nodule of large airway: tracheobronchopathia osteochondroplastica

Dandan Li, Faguang Jin, Yandong Nan, Hua Jiang, Qiao Liu, Hongang Liu, Tao Xin

PDF Pages: 1115-1121 Full Text (819) Reporting Checklist Data Sharing Statement Peer Review File
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## Barriers to palliative care use among surgical patients: perspectives of practicing surgeons across Michigan

Blanche Blumenthal, Christina W. Lee, C. Ann Vitous, Alexandria J. Robbins, Ana C. De Roo, Mary Byrnes, Pasithorn A. Suwanabol

PDF Pages: 1122-1132 Full Text (787) Reporting Checklist COI Form Open Access Get Permission

## Effects of different positive end-expiratory pressure titrating strategies on oxygenation and respiratory mechanics during one- lung ventilation: a randomized controlled trial

Dian Xu, Wei Wei, Lianhua Chen, Shitong Li, Ming Lian

PDF Pages: 1133-1144 Full Text (835) Reporting Checklist Data Sharing Statement COI Form
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## Use of iron sucrose injection in anemia patients with reduced serum iron concentration during hospitalizations of digestive and liver diseases

Cen Hong, Xiangbo Xu, Ruirui Feng, Fernando Gomes Romeiro, Dan Zhang, Zhaohui Bai, Xiaozhong Guo, Xingshun Qi

PDF Pages: 1145-1153 Full Text (1623) Reporting Checklist Data Sharing Statement COI Form
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## Necitumumab plus platinum-based chemotherapy versus chemotherapy alone as first-line treatment for stage IV non-small cell lung cancer: a meta-analysis based on randomized controlled trials

Li Wang, Chen Liao, Meng Li, Shujuan Zhang, Fengming Yi, Yiping Wei, Jiao Yu, Wenxiong Zhang

PDF Pages: 1154-1166 Full Text (809) Reporting Checklist COI Form Open Access Get Permission

## Derivation and validation of a simple nomogram prediction model for all-cause mortality among middle-aged and elderly general population

Lin Liu, Kenneth Lo, Cheng Huang, Ying-Qing Feng, Ying-Ling Zhou, Yu-Qing Huang

PDF Pages: 1167-1179 Full Text (1157) Reporting Checklist Data Sharing Statement COI Form
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### Effects of exogenous probiotics on the gut microbiota and clinical outcomes in critically ill patients: a randomized controlled trial

Jie Wang, Hui Ke, Kai-Xiong Liu, Jie-Ming Qu

PDF Pages: 1180-1190 Full Text (1300) Reporting Checklist Data Sharing Statement COI Form

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### Efficacy of modified rubber band ligation in the treatment of grade III internal hemorrhoids

Lei Jin, Haojie Yang, Kaijian Qin, Ying Li, Can Cui, Renjie Wu, Zhenyi Wang, Jiong Wu

PDF Pages: 1191-1197 Full Text (2779) Reporting Checklist Data Sharing Statement COI Form

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### The characteristics of ICU physical restraint use and related influencing factors in China: a multi-center study

Cuicui Zhang, Di Liu, Qianfeng He

PDF Pages: 1198-1206 Full Text (1201) Reporting Checklist Data Sharing Statement COI Form

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### Remifentanil injected during analepsia shortens length of postanesthesia care unit stay in patients undergoing laparoscopic surgery for endometrial cancer: a randomized controlled trial

Lin-Jia Zhu, Si-Bi Zhang, Xiu-Hong Jiang, Yan Ni

PDF Pages: 1207-1215 Full Text (649) Reporting Checklist Data Sharing Statement Peer Review File

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### Chewing gum promotes bowel function recovery in elderly patients after lumbar spinal surgery: a retrospective single-center cohort study

Xing Du, Yunsheng Ou, Guanyin Jiang, Wei Luo, Dianming Jiang

PDF Pages: 1216-1223 Full Text (695) Reporting Checklist Data Sharing Statement COI Form

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### Factors associated with chronic thoracic spine and low back pain in caregivers of cancer patients

Hideaki Hasuo, Hisaharu Shizuma, Mikihiko Fukunaga

PDF Pages: 1224-1236 Full Text (691) Reporting Checklist Data Sharing Statement Peer Review File

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### Study on dosage range evaluation opioid analgesic for breakthrough pain in cancer patients: a retrospective study

Mahardian Rahmadi, Ulya Madina, Iwan Sulianto, Elfri Padolo, Chrismawan Ardianto, Dinda M. N. Ratri, Agus A. Fauzi, Suharjono

PDF Pages: 1237-1243 Full Text (709) Reporting Checklist Data Sharing Statement COI Form

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### Impact of renin–angiotensin system blocker after aortic valve replacement—a systematic review and meta-analysis

Li Zeng, Junli Li, Jinghan Yang, Yanbiao Liao, Mao Chen

## Current usage status of somatostatin and its analogs and trypsin inhibitors: a real-world study of 34,654 Chinese adult patients with acute pancreatitis

Xufeng Mao, Zhangwei Yang

PDF Pages: 1325-1335 Full Text (796) Reporting Checklist Data Sharing Statement COI Form

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## Rectal diclofenac for prevention of post-endoscopic retrograde cholangiography pancreatitis

Héctor F. Losada, Pablo I. San Martin, Andrés I. Troncoso, Jorge A. Silva

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## Application of shear wave elastography as a diagnostic method for esophageal varices

Wei Zhao, Chen Liu, Liang Zhang, Jing Chong, Ning Yu

PDF Pages: 1342-1350 Full Text (599) Reporting Checklist Data Sharing Statement COI Form

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## Enteral immunonutrition versus enteral nutrition for patients undergoing esophagectomy: a randomized controlled trial

Xiao-Kun Li, Zhuang-Zhuang Cong, Wen-Jie Wu, Yang Xu, Hai Zhou, Gao-Ming Wang, Yong Qiang, Li-Guo Luo, Yi Shen

PDF Pages: 1351-1361 Full Text (2061) Reporting Checklist Data Sharing Statement COI Form

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## Cardiac hemodynamic response to the 6-minute walk test in patients with intestinal carcinoma undergoing bevacizumab treatment

Huiling Huang, Yalin Cao, Yugang Dong, Jiayong Li, Chen Liu, Marvin Owusu-Agyema, Yao Tong, Fengjuan Yao, Baolin Chen, Ling Li, Fawang Du, Xingwei Hu, Xing Wang, Yanhong Deng

PDF Pages: 1362-1369 Full Text (535) Reporting Checklist Data Sharing Statement COI Form

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## The inhibitory effect of Gualou Guizhi Decoction on post-ischemic neuroinflammation via miR-155 in MCAO rats

Jinbo Yang, Xiaoqin Zhu, Haixia Hu, Xinjun Lin

PDF Pages: 1370-1379 Full Text (937) Reporting Checklist Data Sharing Statement COI Form

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## Predictive value of ACEF score for clinical prognosis of elderly patients with ST-segment elevation myocardial infarction after percutaneous coronary intervention

Hongwu Chen, Xiaofan Yu, Xiangyong Kong, Longwei Li, Jiawei Wu, Likun Ma

PDF Pages: 1380-1387 Full Text (507) Reporting Checklist Data Sharing Statement Peer Review File

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## A perspective of the relationship of serum HBV DNA and HBsAg apportioned by the same hepatic parenchyma cell volume with inflammation in the natural history of chronic hepatitis B

Lei Tan, Ze-Qian Wu, Chang Zhao, Shu-Ru Chen, Pei-Pei Wang, Zhi-Liang Gao, Dong-Ying Xie, Kun-Peng Hu, Zhi-Shuo Mo

PDF Pages: 1388-1395 Full Text (536) Reporting Checklist Data Sharing Statement COI Form
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## Changes in self-reported physical activity and health-related quality of life following 3-month astaxanthin supplementation in patients with heart failure: results from a pilot study

Sayaki Ishiwata, Takao Kato, Takatoshi Kasai, Akihiro Sato, Shoichiro Yatsu, Hiroki Matsumoto, Jun Shitara, Azusa Murata, Megumi Shimizu, Shoko Suda, Yuya Matsue, Ryo Naito, Masaru Hiki, Hiroyuki Daida

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## Evaluation of maternal and fetal outcomes in pregnancy complicated with pulmonary arterial hypertension

Qian Zhou, Ping Peng, Xinyan Liu, Juntao Liu, Jinsong Gao, Weilin Chen

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## Temporal changes in Egr-1 and c-fos expression in rat models of myocardial ischemia

Li-Qin Zhai, Xiang-Jie Guo, Ze Li, Run-Feng Sun, Qian-Qian Jin, Ming-Zhe Liu, Hua-Lin Guo, Cai-Rong Gao

PDF Pages: 1411-1420 Full Text (644) Reporting Checklist Data Sharing Statement COI Form
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## Impact of structured advance care planning program on patients' wish items and healthcare utilization

Kwok Ying Chan, Ho Yan Chiu, Desmond Y. H. Yap, Cho Wing Li, Terence Yip, Kwok Wai Tsang, Wai On Tam, Ho Yan Au, Chi Yan Wong, Man Lui Chan, Mau Kwong Sham

PDF Pages: 1421-1430 Full Text (1208) Reporting Checklist Data Sharing Statement COI Form
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## The clinical ability of contrast-enhanced magnetic resonance imaging to predict treatment outcomes for lumbar facet joint pain

Min Cheol Chang, You Gyoung Yi, Hea-Eun Yang, Jang Ho Lee, Ji Hwan Kim, Kyung Hee Do

PDF Pages: 1431-1437 Full Text (523) Reporting Checklist Data Sharing Statement Peer Review File
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## Efficacy and safety of docetaxel and prednisolone chemotherapy in very elderly men with metastatic castration-resistant prostate cancer (mCRPC) in real world: a single institute experience

Kai-Yun Wang, Liang Ma, Lan-Lan Zhang, Yi-Chao Hu, Jun-Hui Jiang, Qi Ma

PDF Pages: 1438-1444 Full Text (679) Reporting Checklist Data Sharing Statement COI Form
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## The utility of the adjusted-OPTIMIZE-HF risk model for predicting in-hospital length of stay in the Chinese population

Yao Wang, Yongcheng Wang, Wenbin Zhang

PDF Pages: 1445-1455 Full Text (495) Reporting Checklist Data Sharing Statement COI Form

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### Knockdown CD44 promote the inflammatory response through the autophagy pathway in mouse models of pulmonary contusion

Songlin Yang, Xianglin Meng, Wei Yu, Dongsheng Fei, Wei Yang, Shishuai Meng, Peiyao Luo, Jianpeng Wang, Shangha Pan, Mingyan Zhao

PDF Pages: 1456-1466 Full Text (576) Reporting Checklist Data Sharing Statement COI Form

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### Risk predictive models for delirium in the intensive care unit: a systematic review and meta-analysis

Xiangping Chen, Yuewen Lao, Yi Zhang, Lijie Qiao, Yiyu Zhuang

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### Changes of lymphatic flow caused by core needle biopsy of axillary sentinel lymph node in a rabbit model

Yiqin Xia, Mingjie Zheng, Lie Chen, Yangyang Cui, Huaxing Huang, Peng Kong, Wenbin Zhou, Hui Xie, Shui Wang

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### Coronavirus disease (COVID 2019): protocol for a living overview of systematic reviews

Cuncun Lu, Tingting Lu, Bei Pan, Qi Wang, Liangying Hou, Qian Zhang, Yunhua Wang, Yihui Wang, Xiuxia Li, Yue Ruan, Lian Chen, Honghao Lai, Tianzhu Qin, Long Ge, Kehu Yang

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### CT-guided percutaneous minimally invasive radiofrequency ablation for the relief of cancer related pain from metastatic non-small cell lung cancer patients: a retrospective study

Xiaoyun Zhou, Hongsen Li, Qing Qiao, Hongming Pan, Yong Fang

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### Glutamine on critical-ill patients: a systematic review and meta-analysis

Yueming Sun, Sainan Zhu, Shuangling Li, Hong Liu

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### *Klebsiella pneumoniae* infection associated septic pulmonary embolism in an emergency department from east China

Xiaobin Zhang, Qian Yang, Bo Gao, Jialu Wang, Lei Tian, Jia Hua, Changqing Zhu, Xiaoye Lu

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### Ipsilateral ultrasound-monitoring technique for reducing malpositions of peripherally inserted central catheters in the intensive care unit

Seunghwan Song, Up Huh, Jae Il Lee, Chung Won Lee, Jung Seop Eom, Hyo-Jeong Kim, Il Jae Wang, Jae-Joon Kim

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## Multidimensional intervention in individuals with mild cognitive impairment: a pilot nonrandomized study

Shaofang Xu, Guilin Meng, Pengfei Chen, Min Fang, Aiping Jin

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## Screening for and combining serum intestinal barrier-related biomarkers to predict the disease severity of AECOPD

Jiuheng Yin, Shuai Wang, Yuan Qiu, Enlai Jiang, Guangsheng Du, Wensheng Wang, Pengyuan Xu, Hua Yang, Mingdong Hu, Weidong Xiao

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## The effect of a novel slow-flow irrigation drainage tube on anastomotic leakage and empyema after the resection of esophageal or gastroesophageal junction cancer

Fengkai Xu, Jie Gu, Yufeng Ou, Yin Li, Yiwei Chen, Di Ge, Chunlai Lu

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## Adjuvant treatment with Angong Niuhuang pills in treating traumatic brain damage: a meta-analysis of randomized controlled trials

Peng-Cheng Zhao, Zhen-Shan Huang, Shao-Nian Xu, Yong-Ming Zhang

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## Ligustrazine induces the colorectal cancer cells apoptosis via p53-dependent mitochondrial pathway and cell cycle arrest at the G0/G1 phase

Yaoyao Bian, Lili Yang, Wei Sheng, Zhengjun Li, Yuying Xu, Wenlin Li, Li Zeng

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## Dynamic contrast-enhanced MRI for response evaluation of non-small cell lung cancer in therapy with epidermal growth factor receptor tyrosine kinase inhibitors: a pilot study

Jae-Hun Kim, Ju Won Lee, Keunchil Park, Myung-Ju Ahn, Jung Won Moon, Soo-Youn Ham, Chin A Yi

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## Beneficial aspects of high dose intravenous vitamin C on patients with COVID-19 pneumonia in severe condition: a retrospective case series study

Bing Zhao, Yun Ling, Jian Li, Yibing Peng, Jun Huang, Yihui Wang, Hongping Qu, Yuan Gao, Yingchuan Li, Bijie Hu, Shuihua Lu, Hongzhou Lu, Wenhong Zhang, Enqiang Mao

### Chinese herbal medicine Buyang Huanwu Decoction combined with acupuncture to treat sequela of apoplexy: a meta-analysis of randomized controlled trials

Meng-Jie Zeng, Lin-Jun Li, Zhi-Quan Wu

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### Comparative efficacy between monoclonal antibodies and conventional drugs in postmenopausal women with osteoporosis: a network meta-analysis

Qingtao Jiang, Feng Zhang, Baoli Zhu, Hengdong Zhang, Lei Han, Xin Liu

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### Serum protein complex profiling reveals heterogeneity of Balanced constitutional population in traditional Chinese medicine through blue native polyacrylamide gel electrophoresis

Fei Tan, Tao Zhang, Xinyan Chen, Tingting Song, Jiamin Yuan, Chen Sun, Fuping Xu, Yanchang Li, Lei Chang, Fuqiang Wang, Chen Shao, Weimin Zhu, Ping Xu, Zhimin Yang

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### Comparison between the first-line and second-line immunotherapy drugs in the progression-free survival and overall survival in advanced non-small cell lung cancer: a systematic review and meta-analysis of randomized controlled trials

Shengyu Wu, Lei Wang, Wei Li, Bin Chen, Yu Liu, Hao Wang, Sha Zhao, Lingyun Ye, Hui Sun, Yayi He

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### Systematic analysis reveals a lncRNA-miRNA-mRNA network associated with dasatinib resistance in chronic myeloid leukemia

Jiawen Luo, Yin Gao, Xiaomin Lin, Xiaoying Guan

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### Study on the relationship between sex hormone changes and erectile dysfunction in patients with chronic prostatitis/chronic pelvic pain syndrome

Donglai Fan, Weipu Mao, Guangchun Wang, Heng Shi, Zonglin Wu, Jinbo Xie, Lei Yin, Tianyuan Xu, Keyi Wang, Bo Peng

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### Vitamin C attenuates vancomycin induced nephrotoxicity through the reduction of oxidative stress and inflammation in HK-2 cells

Wenyun Xu, Zhongan Mao, Bing Zhao, Tongtian Ni, Siyu Deng, Ping Yu, Juan He, Enqiang Mao

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### A retrospective multicenter study comparing bupivacaine and ropivacaine in endoscopic ultrasound guided celiac plexus neurolysis

Yuchong Zhao, Xiaorong Guo, Kaixuan Wang, Qian Chen, Yun Wang, Liangkai Chen, Wei Gao, Bin Cheng, Zhendong Jin

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### Characteristics of cancer patients with COVID-19 in a cancer hospital

Demis N. Lipe, Ahmed Elsayem, Maria T. Cruz-Carreras, Jomol Thomas, Adianes Feliciano, Jenny Ren, Susan M. Gaeta, Eva Rajha, Elisabet Manasanch, Ed Kheder, Patricia Brock, Cielito Reyes-Gibby

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### A new prediction model for acute kidney injury in patients with sepsis

Chenyu Fan, Xiu Ding, Yanli Song

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Kenjiro Ishii, Yasuhiro Tsubosa, Masahiro Niihara, Toshiya Akai, Wataru Soneda

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### Locoregional options in the management of cholangiocarcinoma: single center experience

Hussein Baydoun, Harley Meirovich, Gilbert Maroun, Natalie Coburn, Elizabeth David

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Cencen Wang, Heqing Huang, Chen Zhao, Jiao Zhao, Runji Xiong, Runming Jin, Yan Bai

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### Association of acute normovolemic hemodilution with decreased length of hospital stay in rhesus-negative patients undergoing major cancer surgeries: a retrospective study

Yan Ni, Xia-Hao Ding, Zhi-Jie Xu, Zhen-Feng Zhang, Yang Zhang, Bo Gui

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## A single-center 10-year retrospective study of clinical features and surgical treatment of spinal metastasis from cholangiocarcinoma

Shuzhong Liu, Xi Zhou, Muchuan Wang, Siyuan Yao, Tong Niu, Chengao Gao, Ziquan Li, Zhen Huo, Yipeng Wang, Yong Liu

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Norihisa Yasuda, Koji Goto, Takayuki Mizoguchi, Yoshifumi Ohchi, Shin-Ichi Nureki, Takaaki Kitano

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Jinlin Wang, Yun Wang, Yuchong Zhao, Xiaoli Wu, Min Zhang, Wei Hou, Qian Chen, Bin Cheng

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Saijin Cui, Yaling Zhang, Lu Liu, Yan Li, Rongmiao Zhou, Xi Huang, Shiru Cao, Xiangran Huo, Na Wang

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Juan Xue, Qun Yang

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Xiangyang Yu, Shugeng Gao, Qi Xue, Fengwei Tan, Yushun Gao, Yousheng Mao, Dali Wang, Jun Zhao, Yin Li, Feng Wang, Hong Cheng, Chenguang Zhao, Ding Yang, Juwei Mu

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Jie Liu, Wei Hou, Mithat Gönen, Christina Seluzicki, Susan Qing Li, Jun J. Mao

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## Pingyang Jiangya Fang pretreatment reduces the blood pressure of spontaneously hypertensive rats with Liver-Yang hyperactivity syndrome via ROS/Akt oxidative stress pathway

Zirong Li, Mengyao Wu, Deguo Liu, Xiaoye Wang, Wenli Yang, Yuhong Wang, Changjiang Xiao

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Juan Li, Jing He, Linbo Cai, Mingyao Lai, Qingjun Hu, Chen Ren, Lei Wen, Jian Wang, Jiangfen Zhou, Zhaoming Zhou, Shaoqun Li, Minting Ye, Changguo Shan, Longhua Chen, Cheng Zhou

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Xiang Li, Feng Yuan, Zhenguang Zhang, Juntao Yang, Jing Zhang, Zhipeng Li, Yan Peng, Yuanming Jiang, Wenfang Yi, Jiyao Ma, Wei Zhao, Bo He, Li Wu, Kunhua Wang

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## Dynamic analysis of pulmonary computed tomography (CT) characteristics in cured coronavirus disease 2019 (COVID-19) patients

Yunhui Yang, Zhenghua Zhang, Yuanming Jiang, Zhipeng Li, Hongyuan Yang, Zhi Li, Xiang Li, Juntao Yang, Jing Zhang, Yan Peng, Lin Luo, Wen Chang, Wei Zhao, Yi Wu, Cunwen Ma, Shiping Wang, Yongjian Wen, Fushun Pu, Xuefei Jiang, Lishuang Shen, Zhengyi Zhan, Yong Jin, Qiming Li, Wenfang Yi, Ying Xie, Yanlong Tang, Hao Duan, Kai Yang, Yu Su, Chuncai Wu, Zhongzheng Luo, Peng Wang, Minchang Hong, Shiqiang Yang, Wenyong Bai, Guilin Yu, Shaohua Liu, Zhongmin Nie, Guangbi Song, Dongquan Guo, Xiaobo He, Zhiyu Chen, Kaiyi Xue, Jiyao Ma, Yuchun Wu, Xiaotao Yang, Bo He, Kunhua Wang, Jiangyuan Pi

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Lu Wang, Wuwan Wang, Tingting Shu, Panpan Feng, Rui Xiang, Wei Huang

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Wen-Ying Fu, Hua Yuan, Xiu-Qin Ye, Di-Yan Shou, Wei Zhu

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### Performance verification of a new fibrinogen assay

Xuezheng Li, Yanhong Chen, Jie Zhao, He Liu, Haixin Li

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### Cystatin C level is associated with the recovery of renal function in cancer patients after onset of acute kidney injury

Rui Li, Xia Wang, Xiaoqian Zhao, Xiaohong Zhang, Honghai Chen, Yue Ma, Yandong Liu

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### A randomized trial in the investigation of anxiety and depression in patients with coronavirus disease 2019 (COVID-19)

Feng Zhou, Rong-Rong Wang, Han-Ping Huang, Chun-Ling Du, Chao-Min Wu, Xue-Mei Qian, Wei-Li Li, Ju-Li Wang, Lv-Yan Jiang, Hui-Jia Jiang, Wen-Jie Yu, Ke-Bin Cheng

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### The expression levels of plasma dimethylglycine (DMG), human maternally expressed gene 3 (MEG3), and Apelin-12 in patients with acute myocardial infarction and their clinical significance

Yingna Wei, Bei Wang

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Hai Zhang, Yun Song, Xiaowei Mao, Feng Pan, Yan Pan, Liyan Jiang

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### A low proportion of regulatory T cells before chemoradiotherapy predicts better overall survival in esophageal cancer

Fei Lan, Bin Xu, Jie Li

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### *Tiaochang Xiaoyan extract tablets* ameliorate chronic inflammation by activating macrophage lysosomes in chronic colitis rats

Shiying Wang, Chun Guo, Tao Zhang, Cailing Zhong, Xiying Zhao, Yisheng Su, Wei Wei, Beiping Zhang

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### Dynamic contrast-enhanced MRI of nasopharyngeal carcinoma: correlation of quantitative dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) parameters with hypoxia-inducible factor 1α expression and tumor grade/stage

Lan Liu, Liping Hu, Qiao Zeng, Dexin Peng, Zhiping Chen, Chuansheng Huang, Zhiliang Liu, Qingyi Wen, Fei Zou, Lan Yan

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Yiqin Wang, Chao Liu, Li Zhang, Jijun Li, Lei Zhang, Yong Wang, Hanyu Zhu, Xueying Cao, Di Wu, Jie Wu, Shupeng Lin, Zhe Feng, Guangyan Cai, Xiangmei Chen, Xuefeng Sun

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Tianzhu Liu, Xiaodan Li, Lesheng Huang, Hongyi Li, Kaili Cai, Jinghua Jiang, Nianli Chen, Wanchun Zhang, Jiahui Tang, Meng Zhang, Dan Zhao, Jingzhi Ye, Chengfeng Zhang, Tao He, Bo Liu, Yongsong Ye, Jun Chen

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Jiao Xia, Rongli Wang, Min Tian, Xunlian Wu

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### Coronavirus disease 2019 (COVID-19): two case reports from a family cluster

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Amy H. Ng, Diana M. Molinares, An T. Ngo-Huang, Eduardo Bruera

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Yankang Cui, Chenkui Miao, Aiming Xu, Zengjun Wang, Bianjiang Liu

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Xiaoyan Han, Hua Yang

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Original Article

# Study on dosage range evaluation opioid analgesic for breakthrough pain in cancer patients: a retrospective study

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*Contributions:* (I) Conception and design: M Rahmadi, I Sulianto, E Padolo; (II) Administrative support: I Sulianto, E Padolo, AA Fauzi, S Suharjono; (III) Provision of study materials or patients: I Sulianto, E Padolo; (IV) Collection and assembly of data: U Madina; (V) Data analysis and interpretation: M Rahmadi, U Madina, C Ardianto, DMN Ratri; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

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**Background:** Breakthrough pain is an exacerbation of pain occurring in patients with chronic pain who receive opioid therapy every day. Breakthrough pain has not been routinely recognized, evaluated and treated. This study aimed to analyze the utilization of opiates analgesics, including dose regimentation, frequency of use, and the actual adverse effects in cancer patients with breakthrough pain.

**Methods:** Data were collected by the retrospective method in the period from January to December 2017. Patients involved received opioids around the clock for treating background pain and rescue medication for treating breakthrough pain. The percentage of the rescue medication dose was calculated based on the total daily opioid dose to treat background pain. Descriptive analysis was used.

**Results:** From 335 visits, there were 334 of patient visit where the patient received immediate-release morphine as a rescue medication with a dose percentage between 6.67–60%, and 1 visit where the patient received codeine with a dose percentage of 16.67%. Of 335 visits, 233 patient visits received the right proportion of opioid rescue medication doses, while 102 patient visits received a greater dose proportion than the recommended dose of 5–20%.

**Conclusions:** Immediate-release morphine is the most commonly prescribed analgesic to treat breakthrough pain and used at 6.67–60% of daily dose with the frequency of use between 2 to 6 times a day. There were 189 (56.42%) patient visits when the patient experienced the adverse effects of the opioid. The identified actual adverse effects are constipation, nausea, and vomiting.

**Keywords:** Breakthrough pain; cancer pain; opioid; morphine; dose

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## Introduction

Breakthrough pain (BP) develops from chronic pain. Symptoms of exacerbation came from patients using daily opioid medication. Data from an international survey shows that 65% of cancer patients have BP. In addition, the variability of BP prevalence is high in several countries (1). Even though BP can occur several times in 24 hours, the trigger could unpredictable for cancer patients (2,3). This may be caused by the patient's ignorance of cancer pain (4). Opioid and nonsteroidal anti-inflammatory drugs (NSAIDs) are usually chosen for cancer pain management (2,5). Nowadays, a short-acting opioid is widely used for BP control (6). This therapy also needs adequate assessing and monitoring. Unfortunately, identification, evaluation and prescription for BP are still poorly understood (1). The objective of this study was to evaluate the use of opioid, opioid dose, and the actual adverse effect. We present the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/apm-20-492).

## Methods

This was a retrospective observational study on the visits of patients with cancer at the Palliative Care and Relieved Pain Outpatient Clinic at tertiary care teaching hospital, Dr. Soetomo Hospital in Surabaya. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the local Ethics Committee of the Dr. Soetomo Hospital with serial number 0033/KEPK/II/2018 and individual consent for this retrospective analysis was waived. Data were collected between January and December 2017.

### *Participant*

Patient with cancer diagnosis, undergoing opioid therapy and experiencing BP were included. Patients were excluded from the study according to the following exclusion criteria: hypersensitivity to an opioid. Patient characteristic data recorded were sex, gender, final diagnosis and Karnofsky scale. This study reviewed opioid therapy for BP in 335 patient visits. The therapy profile was taken from the secondary data medical record. Pain intensity used a Numerical Rating Scale (NRS) with a Visual Analogue Scale (VAS) method adapted from the medical record. Pain intensity was considered as a mean pain scale over the last week. Patients with BP have received morphine immediate release (MOIR) tablets or crushed morphine sustained-release tablets (MST) because of national out-of-stock conditions. The percentage of opioid dose for BP was calculated by dividing the opioid dose for BP to the total daily opioid dose in a morphine dose conversion. The appropriate dosage range for BP treatment is between 5–20% of total daily opioid dose consumed (1,7).

### *Data analysis*

A descriptive analysis was used to evaluate the pain scales, patient's opioid therapy, appropriate dose range, other analgesics usage and adverse drug reactions from opioid use. Missing data were shown in the table.

## Results

### *Participant flow and baseline data*

Around 11% of 861 patients visited the Palliative Care Outpatient Clinic at Dr. Soetomo Hospital were treated with an opioid for BP. Those patients made 726 visits between January and December 2017. About 46% of the visits was followed by an opioid regimentation for BP rescue medication. From the total population, 59.41% were woman. Patients aged 45–64 years were 51.49% of the studied population, and around one-third were 20–44 years old. The smallest portion of patients (6%) were aged 65–84 years. The diagnoses were both solid and haematology cancer. Diagnoses were cervical cancer (30.69%), nasopharyngeal cancer (11.88%), acute lymphoblastic leukaemia (ALL) (7.92%), breast cancer (5.94%) and rectal cancer (3.96%). On the Karnofsky scale, 85.15% of the patients scored 50–70%, 10.89% scored 80–100%, 2.97% were unrecorded, and one patient was 0–40% (*Table 1*).

### *Outcomes*

Based on the medical records, patients with moderate pain were 55.52% of the population; severe pain, 29.25%; mild pain, 14.03%; and not recorded, 1.19% as shown in *Table 2*. Type of opioid was consumed: MOIR, MST, codeine, fentanyl patch, and a combination of MST and fentanyl patch. Opioid dose and frequency are displayed in *Table 3*. This table shows that the most commonly used types of opioids are MST 54.33% (n=182), followed by MOIR 23.28% (n=78), and fentanyl 20.60% (n=69). Cancer

**Table 1** Characteristics of patients

| Characteristics | N (%) |
|---|---|
| Sex | |
| Female | 60 (59.4) |
| Male | 41 (40.6) |
| Ages (years)[†] | |
| <20 | 11 (10.9) |
| 20–44 | 32 (31.7) |
| 45–64 | 52 (51.5) |
| 65–84 | 6 (5.9) |
| Final diagnosis | |
| Cervix cancer | 31 (30.7) |
| Nasopharyngeal cancer | 12 (11.9) |
| ALL | 8 (7.9) |
| Breast cancer | 6 (5.9) |
| Rectal cancer | 4 (4.0) |
| Tongue cancer | 4 (4.0) |
| Bladder cancer | 3 (3.0) |
| Osteosarcoma | 3 (3.0) |
| Lung cancer | 3 (3.0) |
| Ovarian cancer | 2 (2.0) |
| Endometrial cancer | 2 (2.0) |
| Prostate cancer | 2 (2.0) |
| LNH | 2 (2.0) |
| Pancreatic head cancer | 2 (2.0) |
| Vulvar cancer | 1 (1.0) |
| Testicular cancer | 1 (1.0) |
| Colon cancer | 1 (1.0) |
| Thyroid cancer | 1 (1.0) |
| Lymphoma cancer | 1 (1.0) |
| Caecum cancer | 1 (1.0) |
| Sinonasal cancer | 1 (1.0) |
| Renal cancer | 1 (1.0) |
| Others[‡] | 9 (8.9) |
| Karnofsky scale[§] | |
| 0–40 | 1 (1.0) |
| 50–70 | 86 (85.1) |
| 80–100 | 11 (10.9) |
| Not recorded | 3 (3.0) |

[†], age range distribution based on modification of the National Cancer Institute guidelines (8); [‡], others: malignant spindle mesenchymal tumor reg clavicula, malignant cell bone, soft tissue tumor, proximal femoral region, malignant spindle cell tumor, chronic myeloid leukemia with hyperleukocytosis, cerebral metastatic neoplasm, salivary duct cancer metastases to the bone and cerebri, conjunctival tumor dd non-Hodgkin lymphoma, upper tract urothelial carcinoma, and hepatoma; [§], Karnofsky performance status scale at first visit. ALL, acute lymphoblastic leukaemia; LNH, lymphoma non-Hodgkin.

patients received BP treatment with an opioid in 335 visits. There were only 5 visits with combination therapy. Patients were treated with MOIR in 92.84% (n=311) of the visits. Some patients received crushed MST 6.87% (n=23) due to a national out-of-stock condition, and one patient received codeine on one visit. The percentage of rescue medication for BP with MOIR was from 6.67% to 60% of the total daily opioid dose. Among them, between 10% and 33.33% were given crushed MST. Also, the patient who received codeine for BP was given 16.67% of the total daily opioid dose. From the result described above, 56.42% (n=189) of patients received an appropriate dosage range, and 43.58% (n=146) received a dose higher than 20% of their regular daily intake.

Patients admitted to non-opioid analgesic drugs and adjuvant analgesics therapy for relief of around-the-clock cancer pain are documented in *Table 4*. Paracetamol was used less than 300 times. It was the most used non-opioid analgesic, followed by meloxicam, at 87 times. Amitriptyline was used more than 300 times as an adjuvant analgesic, followed by gabapentin, at 51 times. This study also provides information about the actual adverse effects of opioid therapy. Constipation, nausea, and vomiting were recorded as adverse effects in 120, 95, and 40 visits, respectively.

## Discussion

In fact, the mechanism of BP episodes is not fully understood. BP pain due to the release of nociceptive factors, such as nerve growth factor (NGF) from sensory and sympathetic neurons that have abnormalities (12). The

**Table 2** Pain intensity patients every visit

| Pain intensity[†] | Subject (n=335) | Percentage (%) |
|---|---|---|
| Mild [1–3] | 47 | 14.03 |
| Moderate [4–6] | 186 | 55.52 |
| Severe [7–10] | 98 | 29.25 |
| Not recorded | 4 | 1.19 |

[†], pain intensity according to the National Institute of Health (9).

prevalence of BP in this study was smaller than in other studies, possibly because of the inclusion and exclusion criteria, and the method of sampling was different (13). Additionally, based on this study less than 50% of cancer patient visits with BP took an opioid for BP. This may be due to pain manifestation being poorly recorded in secondary data. There were more female patients than male patients, which is related to the diagnosis. One-third of the

**Table 3** Opioid regimen

| Type of opioid | Opioid dose | Subject (n) | Opioid dose for BP | Opioid dose for BP/total opioid dose/day (%) | Appropriate dosage range[†‡] (% sample) |
|---|---|---|---|---|---|
| MOIR | 2–15 mg every 6 hours | 22 | 1–10 mg | 12.5–25 | 72.72 |
| | 3–15 mg every 4 hours | 56 | 1–10 mg | 8.33–25 | 94.64 |
| MST | 10–30 mg every 12 hours | 181 | 2.5–10 mg | 8.33–50 | 51.38 |
| | 30 mg every 8 hours | 1 | 10 mg | 11 | 100.00 |
| Fentanyl patch | 12.5–50 µg/hour every 72 hours | 69 | 5–15 mg | 10–60 | 92.75 |
| Codeine | 40 mg every 4 hours | 1 | 20 mg (codeine[§]) | 16.67 | 100 |
| MST and fentanyl | 25 mg every 12 hours and 12.5 µg/hour every 72 hours[¶] | 3 | 10 mg | 13.33 | 100 |
| | 2×15 mg and 25 µg/hour every 72 hours[¶] | 2 | 10 mg | 12.5 | 100 |

[†], appropriate dosage range is between 5–20% based on Cancer Care Ontario (7); [‡], appropriate dosage range is between 5–20% based on International Association for the study of Pain (1); [§], codeine to morphine dose conversion: 200 mg codeine in 24 hours ~ 30 mg morphine in 24 hours (10); [¶], fentanyl to morphine dose conversion: 1 µg/hour fentanyl ~ 2 mg morphine in 24 hours (11). BP, breakthrough pain; MOIR, morphine immediate release; MST, morphine sustained release tablet.

**Table 4** Non-opioid and adjuvant analgesics profile

| Analgesics | Drug dose | Route | Subject (n) |
|---|---|---|---|
| Non-opioid analgesics | | | |
| Paracetamol | 150–500 mg | Oral | 292 |
| Meloxicam | 7.5–15 mg | Oral | 97 |
| Paracetamol + N-acetyl cysteine | 150–500 mg | Oral | 19 |
| Ketoprofen | 100 mg | Rectal | 13 |
| Ibuprofen | 200 mg | Oral | 4 |
| Mefenamic acid | 250–500 mg | Oral | 2 |
| Adjuvant analgesics | | | |
| Amitriptyline | 12.5–25 mg | Oral | 320 |
| Gabapentin | 150–300 mg | Oral | 51 |
| Dexamethasone | 1 mg | Oral | 4 |

patients were diagnosed with cervical cancer. In a previous study, BP in patients with cancer is not linked to gender and age (14). In this study, patients with moderate and severe pain might have a Karnofsky score under 70. The level and frequency of BP episodes are reported that affect the daily activity and the ability to work (15,16). From the previous report, most of the patients with a lower-level Karnofsky scale had a higher BP intensity (16). Previous studies demonstrate similar profiles showing that moderate pain is more likely to be associated with BP than mild pain (14).

Another study presents that the most widely used opioid is MST. A previously reported meta-analysis concludes that morphine administration has beneficial effects. This drug reduces the intensity of pain and has a satisfying effect on the patient (17). The present study noted that patients who were opioid-naive with unstable pain were considered for MOIR therapy. Then, if the pain becomes more stable, therapy was replaced with MST. In addition, another study shows the advantage of using MST is to increase compliance (18). This study showed several patients received a MOIR regimen that was lower than the reference (19). The previous reports prove low-dose morphine is effective in reducing pain with high tolerability and quick onset of action (20-22). Our study demonstrated combination opioid therapy was chosen for patients who had uncontrolled pain with one type of opioid. The fentanyl patch and morphine is an alternative combination therapy in a current clinical situation in this study. The incidence of pain relief in combination therapy is high in a previous study (23), even though this may increase the rate of adverse drug reactions. Our study showed rapid-onset opioid is prescribed for BP pain (1). Also, this study highlighted a high percentage dose of morphine for BP should have required reassessment on the number of episodes of BP, the relation between BP and baseline pain, BP intensity, onset, and duration of BP.

Besides opioid analgesics, other analgesics were given to the cancer patients in the present study. Many patients receive paracetamol for analgesia in BP. Previous studies indicate that paracetamol is not supported by high-quality evidence to prove its effectiveness. However, paracetamol exhibits favorable safety in gastrointestinal tolerance and still widely used (24-26). Almost all the population in this study received amitriptyline as an adjuvant analgesic. Amitriptyline is a potent adjuvant analgesic in malignant or non-malignant neuropathic pain and significantly reduce the VAS score more than other tricyclic antidepressants (TCA) (27). The interpretation of this study is limited by retrospective design study, incomplete data in the medical records. The study did not address the statistical examination. Therefore, multicenter studies could also be prospectively designed to aggressively assess the effectiveness of BP treatment and adjustment an opioid dose individualize.

## Conclusions

This retrospective study conducted by examining the records of 335 patient visits with BP indicates that the majority of the pain scale is moderate and relieved with morphine therapy. The dose to resolve the BP ranges from 6.67% to 60%. Only around 50% of patients receive an appropriate dose. The data indicate that paracetamol and amitriptyline are the most prescribed non-opioid and adjuvant analgesics. In addition, this study suggests that constipation, nausea, and vomiting are the actual adverse effects induced by the utilization of opioids.

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## Footnote

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*Ethical Statement*: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This research was approved by the local Ethics Committee of the Dr. Soetomo Hospital with serial number 0033/KEPK/II/2018 and individual consent for this retrospective analysis was waived.

 

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**" Studi Penggunaan Analgesik Opioid untuk Mengatasi Breakthrough Pain pada Pasien Kanker "**

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**PENELITI LAIN :**
1. **Dr Iwan Sulianto Sp. PD**
2. **Elfri Padolo S.Si., SpFRS., Apt.**
3. **Ulya Madina**

**UNIT / LEMBAGA / TEMPAT PENELITIAN : RSUD Dr. Soetomo Surabaya**

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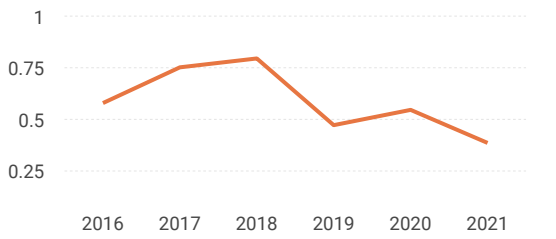


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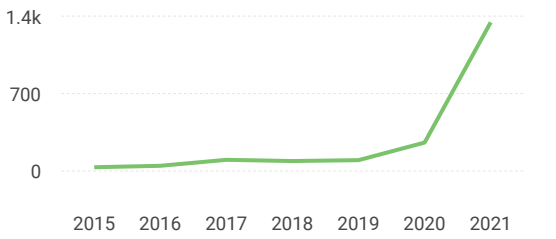


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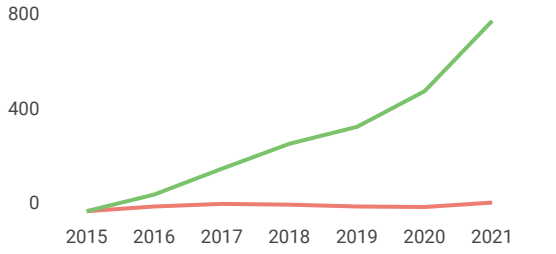


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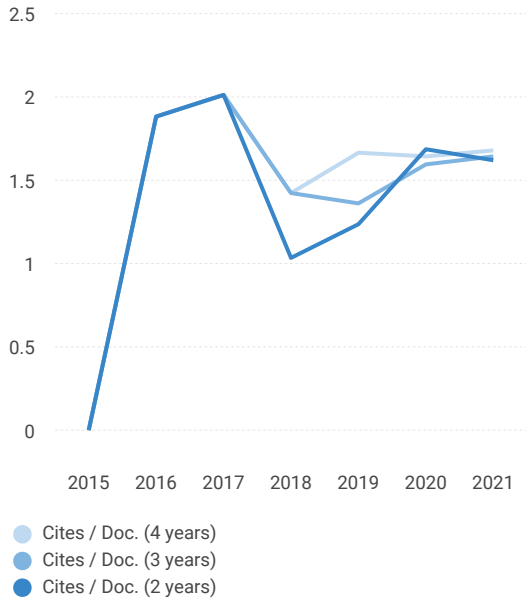


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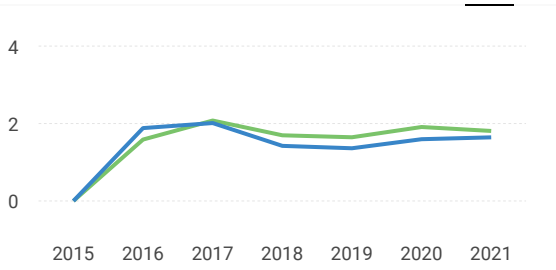


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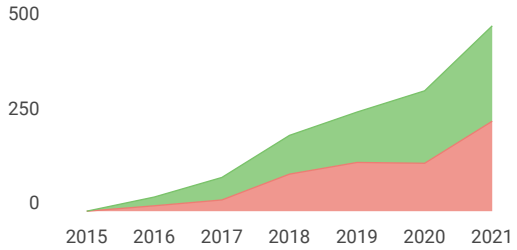



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